



HARPS PHARMACY  
POINT OF CARE  
TEST AND TREAT PROTOCOL



## Description

This protocol will outline the process for performing point-of-care testing (POCT) and treatment at Harps Pharmacy.

## Sofia 2 Analyzer

We will be utilizing the Sofia 2 Point-of-Care analyzer from Quidel for performing Strep, Flu, and COVID testing. After you receive your Sofia analyzer, you should create an account at myquidel.com. MyQuidel allows you to keep your instrument up to date by alerting you of necessary firmware additions/updates via the email you provide.

- Go to quidel.com and click on MyQuidel at the top of the page.
- Click “Get started” under Create your MyQuidel Account
- Enter the email address you would like correspondence to go to (personal email is recommended) and create a password. Open your email and click on the activation link to finish setting up your account.
- Once your account is active, login and click on Manage My Instruments → Register Instrument → Add the serial number from your device.

## Training

Training videos are available via Blackboard in the folder titled Test and Treat, and should be viewed by each staff member who will perform testing (i.e., testing personnel). They include:

- Sofia 2 Training
  - Module 1—Unpacking
  - Module 2—Calibrating
  - Module 4—Performing Quality Control
  - Module 6--Maintenance
- Vital Signs and the Physical Exam
  - Counting Respirations
  - Lymph Node Examination (Pharmacist only)
- Strep
  - Sofia 2 Test Procedure/Running the Test
  - How to Collect a Throat Specimen
- Influenza
  - Sofia 2 Test Procedure/Running the Test
  - How to Collect a Nasal Swab
- COVID
  - Sofia 2 Test Procedure/Running the Test
  - How to Collect a Nasal Swab

The **Test and Treat Training Log** (page 56) serves as a record of personnel who have received training. Training should occur a minimum of annually, and as needed, to ensure proper procedures are up to date.

## Supplies

- Scale (set to kg)
- Pulse oximeter (adult and pediatric)
- Blood pressure monitor (adult and pediatric cuff)
- Tongue depressors

- Thermometer
- Disinfectant
- Biohazard waste sticker
- Clock with a second hand
- Light for viewing patient's throat

### Maintenance of Sofia 2 and CLIA Waiver

Utilize the provided **Sofia 2 Maintenance Log** (page 55) to perform and document calibration and quality control as required.

- Calibration
  - Should be performed **every 30 days**. The Calibration Cassette is supplied with Sofia 2. **Important:** Ensure that the Calibration Cassette is stored in the provided storage pouch between uses to protect from exposure to light.
    1. To check the calibration of Sofia 2, select "Run Calibration" from the Main Menu.
    2. Following the prompts, insert the Calibration Cassette into Sofia 2 and close the drawer. Sofia 2 performs the Calibration Check automatically within one minute with no user input required.
  - Sofia 2 indicates when the Calibration Check is completed.
  - Store the calibration cassette in the foil pouch at all times and do not use after expiration date.
- Quality Control
  - Positive and Negative External Controls should be run:
    - once for each untrained operator
    - once for each new shipment of kits – provided that each different lot received in the shipment is tested
  - The user must first select Run QC on the Main Menu of Sofia 2 and then, when prompted, scan the QC Card (located on kit box). This card provides information specific to the kit lot, including lot number and expiration date.
  - The user will select the desired mode (WALK AWAY) then run the External Control swabs.
  - External Positive and Negative Control swabs are supplied in the kit and should be tested using the Swab Test Procedure provided below. The SARS Positive Control Swab contains SARS antigen. **The Positive Control Swab must be run first**, followed by the Negative Control Swab.
  - When the QC run is complete, each result will be displayed as a ✓ or X on Sofia 2, for the Positive Control and the Negative Control.
  - Do not perform patient tests or report patient test results if either of the QC test results fail.
  - If both the Positive and Negative Controls fail, repeat testing with new Positive and Negative Controls a second time. If only a single Control fails, the user has the option of repeating both the Positive and Negative Controls OR to repeat only the Control that failed. The user may select >> on the Sofia 2 display to skip the Control test that previously passed. The QC Results will show a skipped Control test as >> on Sofia 2.
- Software updates for Sofia 2 should be emailed to the email address you provided when setting up your account at myquidel.com.

- CLIA Certificate of Waiver
  - We are performing point-of-care testing under a CLIA certificate of waiver. Each location must have a waiver that should be displayed in the pharmacy and renewed every 2 years. **Please notify Duane at least 30 days prior to expiration.**

**Scheduling Patients**

Patients should preferably schedule an appointment through PMAP’s CareScheduler via our website or utilizing the QR code. They also have the option of calling the pharmacy to set up an appointment.

- Create a clinic in CareScheduler titled, “Clinical Services.” All vaccines you give at your store + testing services should be added to this single clinic to prevent double bookings.
- For pharmacies who close at 7pm, set clinic hours for 10am-6pm M-F. If your store closes at 6pm, your hours should be 10am-5pm.

We will accept walk-in appointments, but similar to urgent care clinics, patients should be notified that there will most likely be a wait.

- Your script should be “we can make you an appointment for later today or you are welcome to wait, but it may take us \_\_ minutes or so (*depending on how busy you are*) to get you in.”

**Billing**

We are currently able to bill for POC services under our pharmacist NPI with **Arkansas BCBS** only, at this time. Other insurance plans are expected to follow, as we prove the benefit of pharmacist provided patient care services. We will be billing for an Evaluation and Management office visit as well as the Point of Care test. See more detailed info on billing beginning on Page 50.

**Record keeping**

Create a POCT file in the pharmacy filing cabinet and keep the **Intake and Assessment Forms** for 2 years. If a treatment is prescribed, file the prescription with all other prescriptions.

**Statewide Protocols and additional Clinical Pearls**

Thoroughly read through the statewide protocols for both Strep (Page 16-21) and Flu (page 32-36). If you have any concerns/questions, please contact Charity at [cgrisham@harpfood.com](mailto:cgrisham@harpfood.com) before beginning to offer the service.

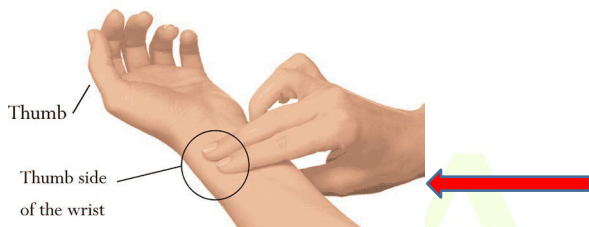
- NOTE: The protocols have been adopted by the State Board of Pharmacy as well as the Arkansas Medical Board. Any updates/changes must be approved by both boards and you will be kept informed of any changes.
- NOTE: The *test and treat* statewide protocols only apply specifically to Flu and Strep, however we are able to *test* for COVID also. There is no prescribed treatment option for COVID that is written per this protocol.
- Weight is not a required part of the physical assessment; however, it may be required for accurate dosing of the prescription and should be recorded on the Assessment Form for best practices.
- There is a typographical error regarding length of therapy of Oseltamivir for Prophylaxis in Children. It should be a length of therapy of 7 days, to match the quantity dispensed of #7.

Influenza Children or Adolescent Prophylaxis		
Weight (kg):		
<input type="checkbox"/> Oseltamivir	Dispense: Weight-based dosing <input type="checkbox"/> ≤15kg: 30mg #7 <input type="checkbox"/> 15-23kg: 45mg #7 <input type="checkbox"/> 23-40kg: 60mg #7 <input type="checkbox"/> >40kg: 75mg #7 No refills	Sigs: <input type="checkbox"/> ≤15kg: 30mg by mouth daily x 5 days <input type="checkbox"/> 15-23kg: 45 by mouth daily x 5 days <input type="checkbox"/> 23-40kg: 60mg by mouth daily x 5 days <input type="checkbox"/> >40kg: 75mg by mouth daily x 5 days
<input type="checkbox"/> Zanamivir	Dispense: <input type="checkbox"/> 1 inhaler No refills	2 inhalations by mouth once daily x 7 days
<input type="checkbox"/> Baloxavir	Dispense: <input type="checkbox"/> 40mg x 1 (if ≥40kg to 79kg) <input type="checkbox"/> 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now

## Vital Signs and the Physical Exam

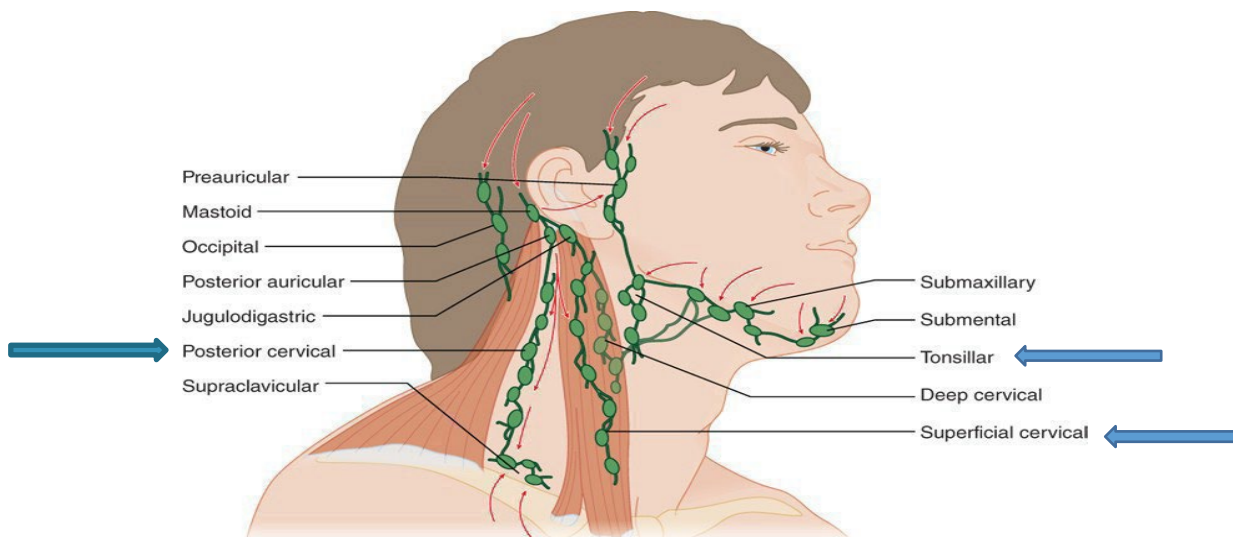
### Respiratory Rate

- This vital sign will be collected by the technician.
- Ask the person to sit upright. You will want to attempt to count the other person's respirations without his knowing. If he knows, he may try to control his breathing. This can give a false respiratory rate.
- A good way to do this discreetly is to give the impression you are taking the radial pulse. You will find the pulse by placing two fingers on the thumb side of the wrist (see picture below) and look for the rise and fall of the chest. While still holding the patient's wrist, start to count his respirations. For 30 seconds, count his breaths (multiply by 2 to get the Respiratory rate).
  - Another method some find helpful is to count respirations while using an automatic blood pressure cuff to take the patient's blood pressure.
- It will be helpful to have a clock with a second hand in the assessment area.
- The pulse rate is not a required vital sign but is a helpful method in order to obtain the respiratory rate.



### Palpating lymph nodes

- The Pharmacist will complete the lymph node exam as part of the Strep assessment.
- You are assessing for tender or swollen lymph nodes in the neck
- For our purposes, only the tonsillar and cervical lymph nodes need assessed (see picture below).
- Under normal circumstances, lymph nodes generally cannot be felt. Swollen lymph nodes may be the size of a pea or a kidney bean.



Source: J.E. Tintinalli, J.S. Stapczynski, O.J. Ma, D. Yealy, G.D. Meckler, D.M. Cline: Tintinalli's Emergency Medicine: A Comprehensive Study Guide, 9th Edition: Copyright © McGraw-Hill Education. All rights reserved.

## Visual Exam of Throat

- Look for exudate (white patches), swelling of tonsils, or redness
- Example of Strep pharyngitis showing tonsillar exudate and erythema:



Source: R.P. Usatine, M.A. Smith, E.J. Mayeaux, Jr., H.S. Chumley  
The Color Atlas and Synopsis of Family Medicine, Third Edition  
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- Example of non-exudative *S. pyogenes*:



Reproduced with permission from Public Health Image Library, Centers for Disease Control and Prevention. Photo contributor: Dr. Heinz F. Eichenwald.



# PEDIATRIC VITAL SIGNS REFERENCE CHART



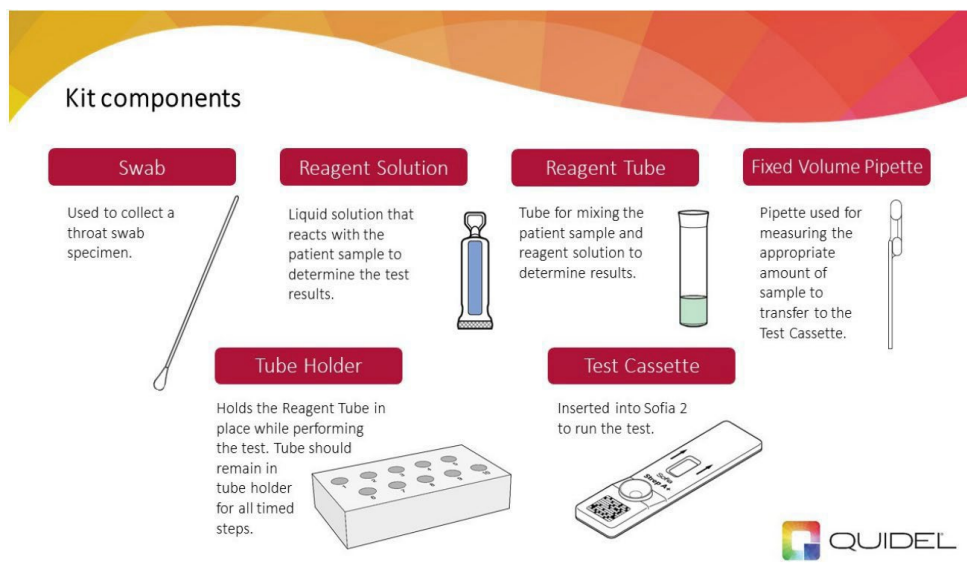
Heart Rate (beats/min)			Respiratory Rate (breaths/min)	
Age	Awake	Asleep	Age	Normal
Neonate (<28 d)	100-205	90-160	Infant (<1 y)	30-53
Infant (1-12 mos)	100-190			
Toddler (1-2 y)	98-140	80-120	Toddler (1-2 y)	22-37
Preschool (3-5 y)	80-120	65-100	Preschool (3-5 y)	20-28
School-age (6-11 y)	75-118	58-90	School-age (6-11 y)	18-25
Adolescent (12-15 y)	60-100	50-90	Adolescent (12-15 y)	12-20
Reference: PALS Guidelines, 2015				
Blood Pressure (mmHg)				
Age		Systolic	Diastolic	Systolic Hypotension
Birth (12 h)	<1 kg	39-59	16-36	<40-50
	3 kg	60-76	31-45	<50
Neonate (96 h)		67-84	35-53	<60
Infant (1-12 mos)		72-104	37-56	<70
Toddler (1-2 y)		86-106	42-63	<70 + (age in years × 2)
Preschool (3-5 y)		89-112	46-72	
School-age (6-9 y)		97-115	57-76	
Preadolescent (10-11 y)		102-120	61-80	<90
Adolescent (12-15 y)		110-131	64-83	
Reference: PALS Guidelines, 2015 For diagnosis of hypertension, refer to the 2017 AAP guidelines Table 4 & 5: <a href="http://pediatrics.aappublications.org/content/early/2017/08/21/peds.2017-1904">http://pediatrics.aappublications.org/content/early/2017/08/21/peds.2017-1904</a>				
Temperature (°C)		Oxygen Saturation (SpO <sub>2</sub> )		
Method	Normal	SpO <sub>2</sub> is lower in the immediate newborn period. Beyond this period, a SpO <sub>2</sub> of <90-92% may suggest a respiratory condition or cyanotic heart disease.		
Rectal	36.6-38.0			
Tympanic	35.8-38.0			
Oral	35.5-37.5			
Axillary	36.5-37.5			
Ranges do not vary with age. <b>Screening:</b> axillary, temporal, tympanic (↓ accuracy) <b>Definitive:</b> rectal & oral (↑ reflection of core temp.) <i>Reference: CPS Position Statement on Temperature Measurement in Pediatrics (2015)</i>				

Dr. Chris Novak & Dr. Peter Gill for [www.pedscases.com](http://www.pedscases.com)  
(Edited March 2020 by Richard He)

# Strep Throat

## Prior to Patient Appointment

1. If you are scheduling an appointment for the patient, enter the patient information into CareScheduler, including **medical** insurance info, if necessary. Inform the patient to bring their insurance card to the appointment as well.
  - > Insurance Name
  - > ID
  - > Medical Group
  - > Is the patient the policy holder? If no:
    - a) Policy holder's name, DOB, and Address (if different than patient's address)
2. If the patient has BCBS medical insurance, login to Availity to check for patient's copay/deductible/coinsurance--see Availity Training document for instructions.
  - > *It is not necessary to check this while on the phone with the patient, unless they request it. You may look this up after you schedule the appointment and have that information ready when the patient arrives.*
3. If the patient is paying cash, refer to the **POCT Pricing Guide for Cash Pay Patients** (page 49) and notify the patient of the cost.
4. Ensure the clinical area is clean and prepared for the appointment with necessary testing supplies.



## Patient Arrival

5. The technician will take out the **Intake Form** of the Pharmacist Assessment, Evaluation and Prescribing Protocol Form: **Strep Throat** for the patient to complete.
6. If patient has BCBS, technician will make a copy of their insurance card.
  - If you did not previously check Eligibility and Benefits in Availity, login to determine if a copay or deductible amount is due.
7. After completion of the form, inform the patient the pharmacist will look over their information and we will let them know when we are ready for them.
8. The technician will prepare the testing area with supplies (if not prepared before patient arrival) for the assessment and testing, and don Personal Protective Equipment (PPE). A mask and gloves, at minimum, should be worn.
  - NOTE: *The reagent solution should not be added to the reagent tube until it is determined the patient is clinically stable and will be tested.*
9. Simultaneously, the pharmacist will determine, based on the patient answers from the Intake Form, if they meet eligibility criteria.
  - NOTE: This is the eligibility criteria for prescribing treatment, not testing. You MAY test the patient if they fall under these exclusion criteria, but they should understand you will NOT be able to prescribe treatment for a positive result.

Age ≥3 years

Not Pregnant

Centor score ≥2

Has not used antibiotics for sore throat or URI within 30 days

GAS POCT is positive

Not Immunocompromised

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response

## Patient Assessment

10. If the patient is deemed eligible to test and treat, the technician will take the patient to the testing area.
- The tech will take vital signs (Weight, Blood pressure, RR, %Oxygen, and Temp), documenting results on the **Assessment Form**.
11. After the vital signs are complete, the technician will bring the Assessment Form to the Pharmacist who will determine if the patient meets clinical stability guidelines. Pharmacist will refer to PCP if clinically unstable.

Physical Assessment	REFER TO PCP if determined clinically unstable or any of the following criteria
<input type="checkbox"/> Blood pressure: _____ <input type="checkbox"/> RR: _____ <input type="checkbox"/> %Oxygen: _____ <input type="checkbox"/> Temperature: _____	<input type="checkbox"/> Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg <input type="checkbox"/> For age 3-9 years: Systolic blood pressure <70 + (age in years × 2) <input type="checkbox"/> Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o <input type="checkbox"/> Low oxygen <90% oxygen via pulse oximetry

12. If the patient is clinically stable, the

pharmacist will proceed to the testing area to assess the patient. The assessment, at minimum, should include:

- A discussion of patient symptoms (what they are, when they began, if they are worsening, improving, or staying the same)
- If known contact with an infectious person
- Centor Score Assessment
  - a) Perform a visual exam of the throat to look for exudate or swelling
    - A head light to view the back of the throat is helpful for visualization
  - b) Palpate the cervical lymph nodes, checking for swelling and asking the patient if tender
  - c) All other information (age, cough present) can be gathered from the Intake Form or asking the patient.
  - d) Calculate the Centor Score:
    - If  $\geq 2$ , it is recommended to test the patient
    - If the patients score is <2, they will not be able to be tested and treated under this protocol.

*NOTE: if <2, It is recommended that you reassess the patient by looking for ANY sign of throat swelling/exudate, or swollen/tender lymph nodes. It would be very unfortunate to test the patient, receive a positive result, and not be able to prescribe an antibiotic; therefore, we recommend erring on the side of positive findings during the physical exam, which will allow you to Test and Treat the patient for a positive result.*

Centor Score Assessment		Interpretation
Age	<input type="checkbox"/> 3-14 years: +1 <input type="checkbox"/> 15-44: 0 <input type="checkbox"/> $\geq 45$ year: -1	Total Points: _____ <input type="checkbox"/> If Score $\geq 2$ , proceed in using protocol <input type="checkbox"/> If Score < 2, excluded from protocol
Exudate or swelling on tonsils	<input type="checkbox"/> No: 0 <input type="checkbox"/> Yes: +1	
Tender/swollen anterior cervical lymph nodes	<input type="checkbox"/> No: 0 <input type="checkbox"/> Yes: +1	
Temperature > 100.4°F	<input type="checkbox"/> No: 0 <input type="checkbox"/> Yes: +1	
Cough	<input type="checkbox"/> Present: 0 <input type="checkbox"/> Absent: +1	

### Sample Collection

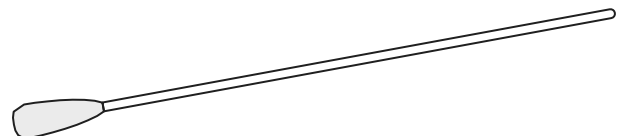
13. Once it has been determined the patient will be tested, the technician will come back to perform the test.
14. Add the reagent solution to the tube utilizing the procedure below:
  - Squeeze ONCE to break the glass ampoule inside the Reagent Solution Bottle.
  - Vigorously shake the Reagent Solution Bottle 5 times to mix the solutions. Solution should turn green after the ampoule is broken.
  - Add Reagent:
    - a) Flick or shake the Reagent Solution Bottle so that all fluid is in the bottom.
    - b) Twist off the tab
    - c) Slowly dispense the Reagent Solution into the Reagent Tube up to the Fill Line.
15. Use the rayon-tipped Swabs provided in the kit to collect the **throat sample**. Collect throat samples by standard clinical methods (see below and watch video on Blackboard). If needed, you may utilize a tongue depressor. Rub the swab on the tonsils and back of the throat, avoiding the tongue and cheeks.
16. Add the patient swab sample to the Reagent Tube. Vigorously mix the solutions by plunging the Swab 5 times in an up and down motion in the Tube.
17. Provide the patient a copy of the **Strep Throat Recommendations** handout.
18. The patient may wait near the pharmacy for test results, or we can call them with their results if they prefer to wait in the car.
19. Leave the swab in the Reagent Tube for 1 minute, then proceed to run the test on Sofia2.

## Preparing the Patient

- Choose a well-lit room.
- Stand directly in front of the patient.
- Place the patient in a comfortable sitting position facing a light source.
- Avoid touching the swab tip to any surface other than the tonsil area.

## Remove the Swab

Remove the sterile swab from the protective packaging. Hold the swab firmly by the handle. **DO NOT** place the swab on any surface once it is removed from the protective packaging.

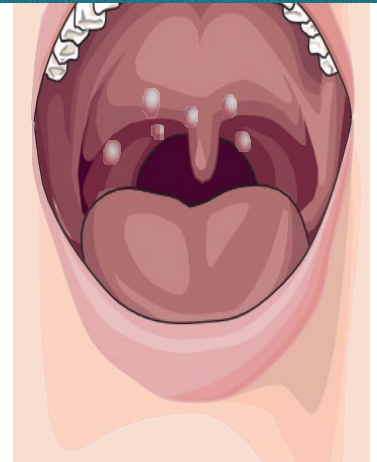


# How To...

## Obtain a Throat Swab Specimen\*

QUIDEL®

\*Instruct patient to say "ahh". The tonsillar area may be reddened, swollen, or have white patches.



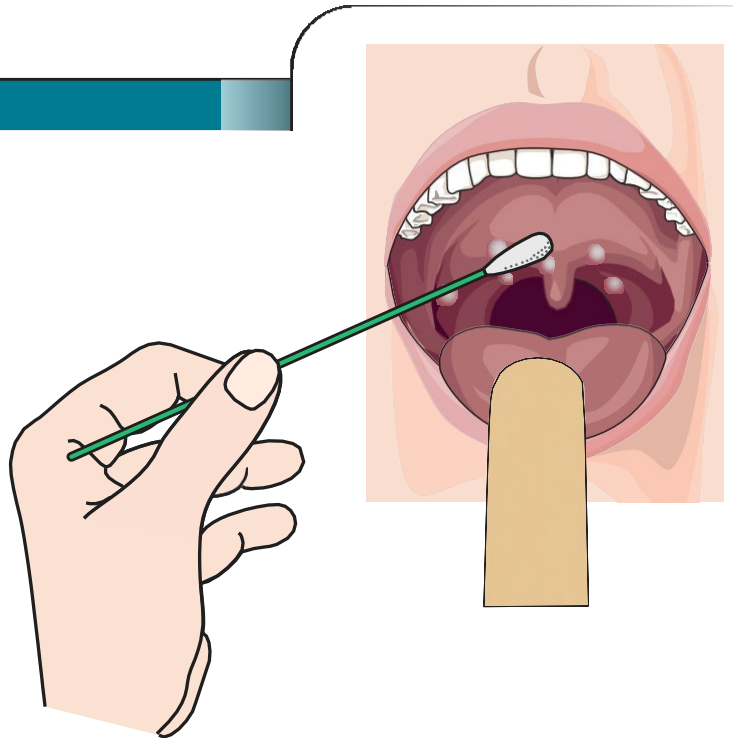
# HowTo...

## Obtain a Throat Swab Specimen (continued)

### Obtaining a Specimen

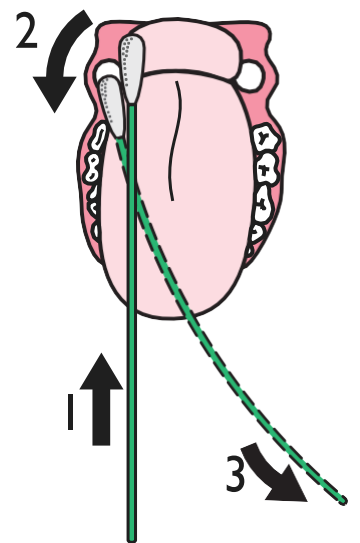
- Direct the tip toward the tonsil area.
- DO NOT touch the swab tip to any other area of the mouth, including the tongue.

*Collect throat swab samples by standard clinical methods. Depress the tongue with a tongue blade. Be careful not to touch the tongue, sides or top of the mouth with the swab. Rub the swab on the back of the throat, on the tonsils, and in any other area where there is redness, inflammation or pus.*



### Obtaining a Specimen (con't.)

- Touch the swab tip to the tonsil area.
- Rub the swab tip quickly and firmly over this area to obtain a good sample.
- Remove swab from mouth (without touching any surface).
- A gag reflex reaction is very common when a good sample is obtained.
- It is recommended that the swab specimen be processed as soon as possible after collection.



## Test Procedure

20. Vigorously mix the solution again by plunging the Swab 5 times in an up and down motion in the Tube.
21. Express as much liquid as possible from the Swab by squeezing the sides of the Tube as the Swab is withdrawn in a complete twisting motion
22. Discard the Swab in accordance with your biohazard waste disposal protocol.
23. Fill the provided Small, Clear 120 µL Fixed Volume Pipette with the patient sample from the Reagent Tube.
  - To fill the Fixed Volume Pipette with the patient sample:
    - FIRMLY squeeze the top bulb.
    - Still squeezing, place the Pipette tip into the patient sample.
    - With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.
24. Firmly squeeze the top bulb to empty the contents of the Small, Clear 120 µL Fixed Volume Pipette into the Test Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.
  - NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.
  - Promptly proceed to the next section, Using Sofia 2, to complete the test

## Using Sofia 2

25. Manually input the **User ID (1234)** using the on-screen keypad.
26. Verify that the correct development mode, WALK AWAY or READ NOW, has been selected.
  - WALK AWAY Mode (utilize when 1 test is being performed)
    - In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time.
  - READ NOW Mode (utilize if multiple tests are being performed)
    - **Critically important:** Allow the test to develop for the **FULL 5 minutes** BEFORE placing it into Sofia 2.
    - The user must first place the Test Cassette onto the counter for 5 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute.
27. Open the Sofia 2 drawer. Insert the prepared Test Cassette into the drawer of Sofia 2 and close the drawer. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen in approximately 5 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute.
28. In walk away mode, the tech should set a timer in the pharmacy to alert when results should be available.

## Interpret Results/Prescribe Treatment

29. After 5 minutes, Sofia 2 will display the results. The pharmacist will read the results and complete the **Assessment Form** with the POCT Result and the Diagnosis of patient, as well as determine the prescribed treatment, if necessary, utilizing the State Protocol.
  - If an invalid result appears with an **X**, the test will need to be performed again with a new patient sample and a new test cassette.

- NOTE: Do NOT only look at the pre-populated prescriptions in the Appendix. They do not have all the information needed for accurate prescribing. Always go first to the **dispensing guidelines** within the protocol for full prescribing info, and then you may utilize the pre-populated prescription.
  - If you are prescribing, bring the rx to the pharmacy for the technician to begin filling. Utilize the pharmacist NPI as the prescriber.
  - Recommended symptomatic treatment should be given for a positive or negative result, as well as when to follow up with a HCP if symptoms do not improve.
30. Notify the patient of results, treatment plan, and follow up if needed.
  31. The patient can proceed to the register for payment for the visit and rx, if prescribed.
  32. If the patient requests written results, the **POC Test Results Form** should be filled out and provided.
  33. File the completed **Intake Form and Assessment Form** in the POCT file folder and keep in the pharmacy for a minimum of 2 years. Prescriptions should be filed with all other prescriptions in the pharmacy.
  34. If the patient has BCBS, bill for the visit and test
    - Follow instructions in the **Guide to Billing Medical Claims** (page 50-54)

# Group A Streptococcal Pharyngitis Treatment Protocol

## I. Purpose

The purpose of this standing order is to reduce morbidity and mortality in Arkansas by allowing Arkansas-licensed pharmacists to initiate therapy including ordering and/or dispensing treatment medications, along with any necessary supplies for administration, to eligible persons who are GAS pharyngitis positive.

## II. Authority

This standing order is issued pursuant to Act 503 of 2021 (HB 1246) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order and/or dispense GAS treatment medications according to the provisions of Arkansas Code § 17-92-101 and the requirements of this standing order.

## III. Screening and Assessment

The Board of Pharmacy will adopt screening assessment and questionnaire (Appendix A) to be used by pharmacists throughout the state. When a patient requests point-of-care testing services, or when a pharmacist, in his or her professional judgement, decides to initiate point-of-care testing and treatment, the patient will be assessed for presenting signs and symptoms that warrant GAS testing, parental consent for individuals under the age of 18, and if appropriate, administer a rapid GAS point-of-care test.

## IV. Dispensing Guidelines

### A. Eligibility Criteria

#### Inclusion:

- Age 3 years and older
- Centor Score  $\geq 2$
- Positive GAS result via CLIA-waived point-of-care RADT

#### Exclusion:

- Immunocompromised as defined
  - Been receiving active cancer treatment for tumors or cancers of the blood
  - Received an organ transplant and are taking medicine to suppress the immune system
  - Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
  - Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
  - Advanced or untreated HIV infection

- Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response
- Pregnant
- Antibiotic therapy prescribed for sore throat or upper respiratory infection within previous 30 days
- Clinically unstable based on the clinical judgement of the pharmacist or any of the following criteria:
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
    - For age 3-9 years: Systolic blood pressure <70 + (age in years × 2)
  - Tachypnea (>25 breaths/min adult or >20 breaths/min <18 y/o)
  - Oxygen saturation (SpO<sub>2</sub>) <90% via pulse oximetry

## **B. Contraindications**

Do not administer amoxicillin to an individual with a known hypersensitivity to penicillin or any component of the formulation

Do not administer cephalexin to an individual with a known hypersensitivity to cephalexin, other cephalosporins, or any component of the formulation

Do not administer azithromycin to an individual with a known hypersensitivity to azithromycin, erythromycin, other macrolide (e.g., azalide or ketolide) antibiotics, or any component of the formulation.

Do not administer azithromycin to an individual with a history of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

## **C. Product Availability**

Streptococcal pharyngitis treatment products that may be dispensed/provided under this standing order. Following dosing below, pharmacist can dispense any commercially available product form (tablet, capsule, suspension) based on availability and patient preference.

### **1<sup>st</sup> line Treatment**

- Amoxicillin
  - Adults: 1000mg by mouth once daily for 10 days
  - Children <20kg: 50mg/kg by mouth once daily for 10 days
- Penicillin V, oral
  - Adults: 500mg twice daily for 10 days
  - Children: 250 mg twice daily for 10 days

### **2<sup>nd</sup> Line Treatment or PCN allergy alternative**

- Cephalexin
  - Adults: 500 mg by mouth twice daily for 10 days
  - Children <25kg: 20mg/kg/dose twice daily for 10 days

### **3<sup>rd</sup> Line Treatment if PCN allergy or equivalent exclusions to first or second line treatment options**

- Azithromycin 500 mg by mouth Day 1 and 250 mg by mouth Days 2-5
- Children <40kg: Azithromycin 12mg/kg per day for 5 days

### **Over-the-Counter Adjunctive Treatment**

- Recommend adjunctive treatment as needed for symptom relief and use of weight-based dosing for children.
  - Acetaminophen 650 mg Q4-6H PRN (MAX 3250 mg/day)
  - Ibuprofen 200 mg Q4-6H PRN X10D for pain or X3D for fever  
Can titrate to 400 mg if needed (MAX 1200 mg/day)

## **D. Warnings/Precautions**

### **1. Amoxicillin**

- *Concerns related to adverse effects:*
  - Anaphylactic/hypersensitivity reactions: Serious and occasionally severe or fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy, including amoxicillin, especially with a history of beta-lactam hypersensitivity (including severe reactions with cephalosporins) and/or a history of sensitivity to multiple allergens.
  - Superinfection: Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months post antibiotic treatment.
- *Disease-related concerns:*
  - Infectious mononucleosis: A high percentage of patients with infectious mononucleosis develop an erythematous rash during amoxicillin therapy; avoid use in these patients.
  - Renal impairment: Use with caution in patients with renal impairment; dosage adjustment recommended in patients with GFR <30 mL/minute. Avoid extended release 775 mg tablet and immediate release 875 mg tablet in patients with GFR <30 mL/minute or patients requiring hemodialysis.
- *Dosage form specific issues:*
  - Benzyl alcohol and derivatives: Some dosage forms may contain sodium benzoate/benzoic acid; benzoic acid (benzoate) is a metabolite of benzyl

alcohol; large amounts of benzyl alcohol ( $\geq 99$  mg/kg/day) have been associated with a potentially fatal toxicity (“gaspings syndrome”) in neonates; the “gaspings syndrome” consists of metabolic acidosis, respiratory distress, gasping respirations, CNS dysfunction (including convulsions, intracranial hemorrhage), hypotension, and cardiovascular collapse (AAP ["Inactive" 1997]; CDC 1982); some data suggests that benzoate displaces bilirubin from protein binding sites (Ahlfors 2001); avoid or use dosage forms containing benzyl alcohol derivative with caution in neonates. See manufacturer's labeling.

- Chewable tablets: May contain phenylalanine; see manufacturer's labeling.

## 2. Penicillin V

- *Concerns related to adverse effects:*
  - Anaphylactic/hypersensitivity reactions: Serious and occasionally severe or fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy, especially with a history of beta-lactam hypersensitivity or history of sensitivity to multiple allergens.). Use with caution in asthmatic patients. If a serious reaction occurs, treatment with supportive care measures and airway protection should be instituted immediately.
  - Superinfection: Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months postantibiotic treatment.
- *Disease-related concerns:*
  - Renal impairment: Use with caution in patients with severe renal impairment.
  - Seizure disorders: Use with caution in patients with a history of seizure disorder; high levels, particularly in the presence of renal impairment, may increase risk of seizures.
- *Other warnings/precautions*
  - Prolonged use: Extended duration of therapy or use associated with high serum concentrations (eg, in renal insufficiency) may be associated with an increased risk for some adverse reactions (neutropenia, hemolytic anemia, serum sickness).

## 3. Cephalexin

- *Concerns related to adverse effects:*
  - Hypersensitivity: Allergic reactions (e.g., rash, urticaria, angioedema, anaphylaxis, erythema multiforme, Stevens-Johnson syndrome, toxic

epidermal necrolysis [TEN]) have been reported. If an allergic reaction occurs, discontinue immediately and institute appropriate treatment.

- Elevated INR: May be associated with increased INR, especially in nutritionally deficient patients, prolonged treatment, hepatic, or renal disease.
- Penicillin allergy: Use with caution in patients with a history of penicillin allergy, especially IgE-mediated reactions (e.g., anaphylaxis, angioedema, urticaria).
- Seizure disorder: Use with caution in patients with a history of seizure disorder; high levels, particularly in the presence of renal impairment, may increase risk of seizures.
- Superinfection: Prolonged use may result in fungal or bacterial superinfection, including *C. difficile*-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed >2 months post antibiotic treatment.

- *Disease-related concerns:*

- Renal impairment: Use with caution in patients with renal impairment; modify dosage in severe impairment.

- *Other warnings/precautions:*

- Direct Coombs tests: Positive direct Coombs tests and acute intravascular hemolysis has been reported. If anemia develops during or after therapy, discontinue use and work up for drug-induced hemolytic anemia.

#### 4. Azithromycin

- *Concerns related to adverse effects:*

- Superinfection: Prolonged use may result in fungal superinfection.

- *Disease-related concerns:*

- Bronchiolitis obliterans: When studied to prevent bronchiolitis obliterans syndrome in patients with hematologic malignancy who underwent allogeneic hematopoietic cell transplantation, rates of cancer relapse and mortality were increased among patients receiving long-term azithromycin, leading to early trial termination (Bergeron 2017; FDA Drug Safety Communication 2018).
- Gonorrhea/syphilis: May mask or delay symptoms of incubating gonorrhea or syphilis, so appropriate culture and susceptibility tests should be performed prior to initiating a treatment regimen.
- Myasthenia gravis: Use with caution in patients with myasthenia gravis; exacerbation and new onset of symptoms have occurred.

- *Special populations:*
  - Infants: Use of azithromycin in neonates and infants <6 weeks of age has been associated with infantile hypertrophic pyloric stenosis (IHPS); the strongest association occurred with exposure during the first 2 weeks of life; observe for nonbilious vomiting or irritability with feeding (Eberly 2015). The risks and benefits of azithromycin use should be carefully considered in neonates; some experts recommend avoidance except for in the treatment of pertussis or *C. trachomatis* pneumonia; specific risk-benefit ratio should be considered before use for *Ureaplasma* spp. eradication (Meyers 2020).
- *Dosage form specific issues:*
  - Oral suspensions: Immediate release and extended-release suspensions are not interchangeable.

#### **E. Documentation**

Patient records must be furnished to a health care practitioner designated by the patient upon the request of the patient. Documentation may include, but is not limited to presenting signs and symptoms that warrant strep testing, parental consent for individuals under the age of 18, and results of rapid diagnostic test(s). Maintain records of all patients receiving services for two (2) years.

## INTAKE FORM

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: ***Strep Throat***

PATIENT INFORMATION		
Name:	Date of Birth:	Age:
Address:	City/State/Zip:	
Email Address:	Phone:	
Primary Care Provider:		
Medication allergies?		
Current medications? (prescription, over-the-counter, herbals, topical medications, pain or allergy medication, and any supplements/vitamins)		
Treatments tried for the current condition (if none please indicate N/A):		
Symptoms:		

PATIENT ELIGIBILITY		
1. Are you 3 years of age and older?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Have you received antibiotics for sore throat or upper respiratory infection within the past 30 days?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Are you pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Have you ever been diagnosed with a weakened immune system? (e.g. cancer, transplant, or long term steroids)	<input type="checkbox"/> Yes*	<input type="checkbox"/> No
	*Pharmacists refer to page 2, #4 for criteria	

Consent and Waiver: I consent to the staff to administer Strep A+ Fluorescent Immunoassay (FIA) test. I fully release and discharge Harps pharmacy, its affiliations, and their officers, and employees from any illness, injury, loss, or damage that may result there from. I consent the release of medical information when necessary for medical protocol or disease tracking purposes. I authorize and request payment of medical benefits directly to this provider. I agree that the authorization will cover all medical services rendered until I revoke the authorization. I agree to be charged the usual and customary charge for the provided service if coverage is denied, or any copay or deductible that results.

**Patient Signature (or Guardian, if <18)** \_\_\_\_\_ **Date** \_\_\_\_\_

*When complete, please return the form to pharmacy staff along with insurance information*

**ASSESSMENT FORM FOR STREP -- FOR PHARMACY STAFF ONLY--**

<b>Physical Assessment</b>		<b>REFER TO PCP</b> if determined clinically unstable or any of the following criteria
<input type="checkbox"/> Weight (in kg): _____ <input type="checkbox"/> Blood pressure: _____ <input type="checkbox"/> RR: _____ <input type="checkbox"/> %Oxygen: _____ <input type="checkbox"/> Temperature: _____		<input type="checkbox"/> Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg <input type="checkbox"/> For age 3-9 years: Systolic blood pressure <70 + (age in years × 2) <input type="checkbox"/> Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o <input type="checkbox"/> Low oxygen <90% oxygen via pulse oximetry
<b>Centor Score Assessment</b>		<b>Interpretation</b>
Age	<input type="checkbox"/> 3-14 years: +1 <input type="checkbox"/> 15-44: 0 <input type="checkbox"/> ≥ 45 year: -1	Total Points: _____  <input type="checkbox"/> If Score ≥ 2, proceed in using protocol <input type="checkbox"/> If Score < 2, excluded from protocol
Exudate or swelling on tonsils	<input type="checkbox"/> No: 0 <input type="checkbox"/> Yes: +1	
Tender/swollen anterior cervical lymph nodes	<input type="checkbox"/> No: 0 <input type="checkbox"/> Yes: +1	
Temperature > 100.4°F	<input type="checkbox"/> No: 0 <input type="checkbox"/> Yes: +1	
Cough	<input type="checkbox"/> Present: 0 <input type="checkbox"/> Absent: +1	
<b>CLIA-waived POCT Result</b>		<input type="checkbox"/> Positive for GAS – continue <input type="checkbox"/> Negative for GAS – refer to PCP + Symptomatic Treatment

Pharmacist Interpretation of qualifying questions and physical assessment; refer to PCP as appropriate. Exclusion criteria does not preclude from testing services. **Refer to PCP for treatment if:**

- |   |                     |
|---|---------------------|
| 1. If younger than 3 years old  | <b>REFER TO PCP</b> |
| 2. If patient has taken antibiotics for sore throat or URI in the last 30 days  | <b>REFER TO PCP</b> |
| 3. If patient is pregnant   | <b>REFER TO PCP</b> |
| 4. If patient is immunocompromised  | <b>REFER TO PCP</b> |
| a. Been receiving active cancer treatment for tumors or cancers of the blood  |                     |
| b. Received an organ transplant and are taking medicine to suppress the immune system   |                     |
| c. Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system                               |                     |
| d. Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)  |                     |
| e. Advanced or untreated HIV infection  |                     |
| f. Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response |                     |
| 5. CLIA-waived POCT result is negative for GAS  | <b>REFER TO PCP</b> |

**Treat using protocol if:**

- Age 3 years and older
- Centor Score ≥ 2
- Positive GAS result via CLIA-waived point-of-care RADT

<b>Diagnosis of Patient:</b>		
<input type="checkbox"/> Strep ADULT ≥18 year	<input type="checkbox"/> Strep CHILD/ADOLESCENT	<input type="checkbox"/> Refer to PCP

\*the following can act as the prescription

Treatment Options		
<b>Streptococcal pharyngitis ADULT &gt;18</b>		
Strep first line treatment options:		
<input type="checkbox"/> Amoxicillin	Dispense: <input type="checkbox"/> 500mg #20 <input type="checkbox"/> 1000mg #10 No refills	Sig: 500mg by mouth twice daily for 10 days OR Sig: 1000mg by mouth daily for 10 days
<input type="checkbox"/> Penicillin VK	Dispense: <input type="checkbox"/> 500mg #20 No refills	Sig: 500mg by mouth twice daily for 10 days
2 <sup>nd</sup> Line Treatment or Penicillin allergy alternative		
<input type="checkbox"/> Cephalexin	Dispense <input type="checkbox"/> 500mg #20 No refills	Sig: 500mg by mouth BID for 10 days
3 <sup>rd</sup> Line Treatment for Penicillin allergy or equivalent		
<input type="checkbox"/> Azithromycin	Dispense <input type="checkbox"/> 250mg #6 No refills	Sig: (500mg) by mouth on day 1, then (250 mg) po days 2-5
Symptomatic treatments (over the counter)		
<input type="checkbox"/> Acetaminophen regular strength (325mg) → 650 mg q4-6hr prn (MAX 3250 mg/day) <input type="checkbox"/> Ibuprofen → 200mg q4-6h prn (400mg if no response to 200mg) (MAX 1200mg/day x10 days for pain or x 3 days for fever) <input type="checkbox"/> Lozenges/drops containing menthol, dyclonine, benzocaine, or hexylresorcinol <input type="checkbox"/> Throat spray containing phenol or benzocaine <input type="checkbox"/> Hot/cold liquids or foods → cold food provide hydration and numbing, hot foods feel good on sore throat. SOFT FOODS preferable to rough or hard foods <input type="checkbox"/> Tea/honey → coats throat to provide relief of pain and irritation.		

Patient: \_\_\_\_\_ DOB: \_\_\_\_\_

Prescribed by: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

\*the following can act as the prescription

Treatment Options		
<b>Streptococcal pharyngitis CHILDREN AND ADOLESCENTS age 3-17</b>		
<b>Patient weight in kg:</b>		
First line treatment option		
<input type="checkbox"/> Amoxicillin	Dispense: <input type="checkbox"/> _____ __mg (50mg/kg) #10 doses No refills	<b>*MAX daily dose 1,000mg/day</b> Sig: 50mg/kg by mouth Daily x10 days
<input type="checkbox"/> Penicillin VK	Dispense <input type="checkbox"/> 250mg #20 doses No refills	Sig: 250mg by mouth twice daily for 10 days
2 <sup>nd</sup> Line Treatment or Penicillin allergy alternative		
<input type="checkbox"/> Cephalexin	Dispense <input type="checkbox"/> _____ __mg (20mg/kg) #20 doses No refills	<b>*MAX 500mg per dose</b> Sig: 20mg/kg/dose by mouth twice daily for 10 days
3 <sup>rd</sup> Line Treatment		
<input type="checkbox"/> Azithromycin	Dispense <input type="checkbox"/> _____ __mg (12mg/kg) #5 doses No refills	<b>*MAX 500mg per dose</b> Sig: 12mg/kg/dose by mouth daily for 5 days
Symptomatic treatments (over the counter)		
<input type="checkbox"/> Acetaminophen regular strength (325mg) → 325 mg q4-6hr prn (MAX 1,625 mg/day) OR _____mg q4-6h prn 10-15 mg/kg/dose MAX 75 mg/kg/day not to exceed 4,000 mg/day <input type="checkbox"/> Ibuprofen → for pain _____ mg q6-8hr if <50kg 4-10 mg/kg/dose (MAX single dose 400mg MAX daily 40mg/kg/day) For fever: _____mg q6-8h (MAX daily dose is 40mg/kg/day up to 1,200mg. MAX single dose 400mg ) <input type="checkbox"/> Lozenges/drops containing menthol, dyclonine, benzocaine, or hexylresorcinol <input type="checkbox"/> Throat spray containing phenol or benzocaine <input type="checkbox"/> Hot/cold liquids or foods→ cold food provide hydration and numbing, hot foods feel good on sore throat. SOFT FOODS preferable to rough or hard foods <input type="checkbox"/> Tea/honey → coats throat to provide relief of pain and irritation		

Patient: \_\_\_\_\_ DOB: \_\_\_\_\_

Prescribed by: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**References:**

1. Infectious Diseases Society of America. Influenza Guidelines. <http://www.idsociety.org>
2. LexiComp. Wolters Kluwer Clinical Drug Information. <http://online.lexi.com>

## Strep Throat Recommendations

### Positive Result:

- Most people have mild illness. Young children (5-15 years old), parents of school aged children, and adults who are often in contact with children are at increased risk.
- Wash your hands often with soap and water for at least 20 seconds to keep from spreading strep. Use alcohol-based hand rub if soap and water are not available.
- Antibiotics can decrease how long someone is sick, decrease symptoms, and prevent the spread of bacteria or serious complications.
- You should start feeling better in 1 to 2 days after starting antibiotics. Contact your health care provider if you are not feeling better after taking antibiotics for 48 hours.
- If you are sick with strep throat, stay home and avoid contact with others except for medical care.
- You should stay home for at least 24 hours after your fever is gone (without the need to use a fever reducing medication) AND after you have taken antibiotics for at least 12 hours.

### Negative Result:

This cannot rule out the strep or other illness. If symptoms continue or worsen, follow up with a healthcare provider is warranted.

### Know the Signs

In general, strep is a mild infection that can be very painful.

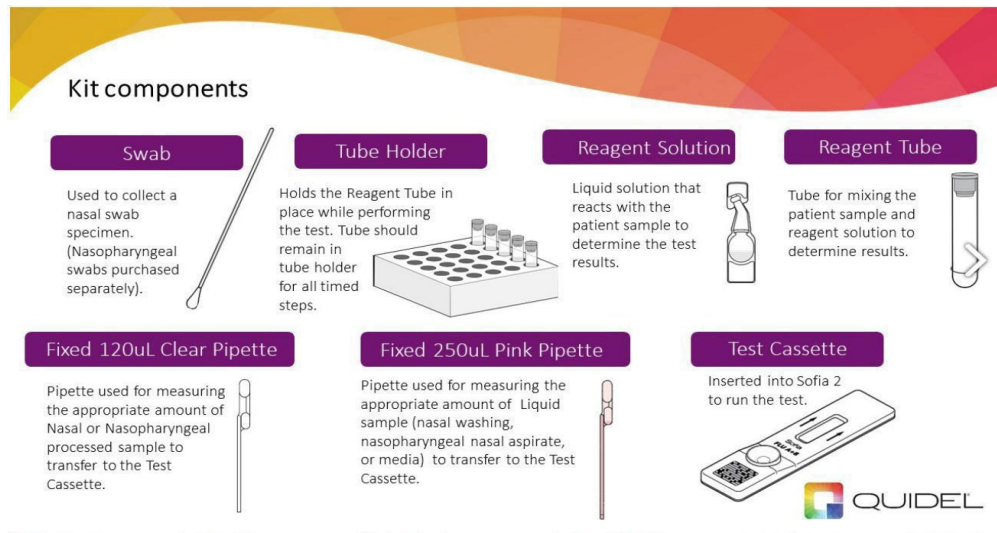
Usually includes symptoms of:	Does not usually include:
<ul style="list-style-type: none"> <li>• Abrupt onset of sore throat</li> <li>• Pain when swallowing</li> <li>• Fever</li> <li>• Red and swollen tonsils sometimes with white patches or streaks of pus</li> <li>• Tiny red spots on the roof of the mouth</li> <li>• Swollen lymph nodes in the front of the neck</li> <li>• Rash (Scarlett fever)</li> </ul>	<ul style="list-style-type: none"> <li>• Cough</li> <li>• Runny Nose</li> <li>• Hoarseness</li> <li>• Conjunctivitis (Pink Eye)</li> </ul>

*All information obtained from <https://www.cdc.gov/groupastrep/diseases-public/strep-throat.html>*

# Influenza

## Prior to Patient Appointment

1. If you are scheduling an appointment for the patient, enter the patient information into CareScheduler, including **medical** insurance info, if necessary. Inform the patient to bring their insurance card to the appointment as well.
  - > Insurance Name
  - > ID
  - > Medical Group
  - > Is the patient the policy holder? If no:
    - a) Policy holder's name, DOB, and Address (if different than patient's address)
2. If the patient has BCBS medical insurance, login to Availity to check for patient's copay/deductible/coinsurance--see Availity Training document for instructions.
  - > *It is not necessary to check this while on the phone with the patient, unless they request it. You may look this up after you schedule the appointment and have that information ready when the patient arrives.*
3. If the patient is paying cash, refer to the **POCT Pricing Guide for Cash Pay Patients** and notify the patient of the cost.
4. Ensure the clinical area is clean and prepared for the appointment with necessary testing supplies.



## Patient Arrival

5. The technician will take out the **Intake Form** of the Pharmacist Assessment, Evaluation and Prescribing Protocol Form: **Influenza** for the patient to complete.
6. If patient has BCBS, technician will make a copy of their insurance card.
  - If you did not previously check Eligibility and Benefits in Availity, login to determine if a copay or deductible amount is due.
7. After completion of the form, inform the patient the pharmacist will look over their information and we will let them know when we are ready for them.
8. The technician will prepare the testing area with supplies (if not prepared before patient arrival) for the assessment and testing, and don Personal Protective Equipment (PPE). A mask and gloves, at minimum, should be worn.
  - NOTE: *The reagent solution should not be added to the reagent tube until it is determined the patient is clinically stable and will be tested.*
9. Simultaneously, the pharmacist will determine, based on the patient answers from the Intake Form, if they meet eligibility criteria.
  - NOTE: This is the eligibility criteria for prescribing treatment, not testing. You MAY test the patient if they fall under these exclusion criteria, but they should understand you will NOT be able to prescribe treatment for a positive result

Age ≥3 years

Not Pregnant

Symptoms <48 hours

No history of allergic reaction to influenza treatment

Has not used antiviral therapy for influenza within 30 days

Not Immunocompromised

## Patient Assessment

10. If the patient is deemed eligible to test and treat, the technician will take the patient to the testing area.
  - The tech will take vital signs (Weight, Blood pressure, RR, %Oxygen, and Temp), documenting results on the **Assessment Form**.
11. After the vital signs are complete, the technician will bring the Assessment Form to the Pharmacist who will determine if the patient meets clinical stability guidelines. Pharmacist will refer to PCP if clinically unstable.

Physical Assessment	REFER TO PCP if determined clinically unstable or any of the following criteria
<input type="checkbox"/> Blood pressure: _____ <input type="checkbox"/> RR: _____ <input type="checkbox"/> %Oxygen: _____ <input type="checkbox"/> Temperature: _____	<input type="checkbox"/> Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg <input type="checkbox"/> For age 3-9 years: Systolic blood pressure <70 + (age in years × 2) <input type="checkbox"/> Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o <input type="checkbox"/> Low oxygen <90% oxygen via pulse oximetry

12. If the patient is clinical stable, the pharmacist will proceed to the testing area to assess the patient. The assessment, at minimum, should include:
  - A discussion of patient symptoms (what they are, when they began, if they are worsening, improving, or staying the same)
  - Any known exposure to a person with illness
  - Vaccination status

## Sample Collection

13. Once it has been determined the patient will be tested, the technician will come back to perform the test.
14. Add the reagent solution to the tube. **Swirl the Reagent Tube to dissolve its contents.**
15. We will be performing a **nasal swab** sample using the nasal swab supplied in the kit. To collect a nasal swab sample, carefully insert the swab (provided in the kit) into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.
  - *See Blackboard video for swab procedure technique.*
  - *NOTE: this is a nasal swab only. It is not necessary to perform a nasopharyngeal collection.*
16. Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.
17. Provide the patient a copy of the **Influenza Recommendations** handout.
18. The patient may wait near the pharmacy for test results, or we can call them with their results if they prefer to wait in the car.
19. Leave the Swab in the Reagent Tube for **1 minute**, then proceed to run the test on Sofia 2.

## Test Procedure

20. Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.
21. Fill the provided Small, Clear 120 µL Fixed Volume Pipette with the patient sample from the Reagent Tube.
  - To fill the Fixed Volume Pipette with the patient sample:
    - FIRMLY squeeze the top bulb.
    - Still squeezing, place the Pipette tip into the patient sample.
    - With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.
22. Firmly squeeze the top bulb to empty the contents of the Small, Clear 120 µL Fixed Volume Pipette into the Test Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.
  - NOTE: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.
  - Promptly proceed to the next section, Using Sofia 2, to complete the test.

## Using Sofia 2

23. Manually input the **User ID (1234)** using the on-screen keypad.
24. Verify that Sofia 2 is set to the desired mode: WALK AWAY or READ NOW
  - WALK AWAY Mode (utilize when 1 test is being performed)
    - In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time.
  - READ NOW Mode (utilize if multiple tests are being performed)
    - **Critically important:** Allow the test to develop for the **FULL 15 minutes** BEFORE placing it into Sofia 2.
    - The user must first place the Test Cassette onto the counter for 15 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute.
25. Open the Sofia 2 drawer. Insert the prepared Test Cassette into the drawer of Sofia 2 and close the drawer. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen in 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute.
26. In walk away mode, the tech should set a timer in the pharmacy to alert when results should be available.

## Interpret Results/Prescribe Treatment

27. After 15 minutes, Sofia 2 will display the results. The pharmacist will read the results and complete the **Assessment Form** with the POCT Result and the Diagnosis of patient, as well as determine the prescribed treatment, if necessary, utilizing the State Protocol.
  - If an invalid result appears with an **X**, the test will need to be performed again with a new patient sample and a new test cassette.
  - NOTE: *Do NOT only look at the pre-populated prescriptions in the Appendix. They do not have all the information needed for accurate prescribing. Always go first to the **dispensing guidelines** within the protocol for full prescribing info, and then you may utilize the pre-populated prescription.*
  - If you are prescribing, bring the rx to the pharmacy for the technician to begin filling. Utilize the pharmacist NPI as the prescriber.

- Recommended symptomatic treatment should be given for a positive or negative result, as well as when to follow up with a HCP if symptoms do not improve.
28. Notify the patient of results, treatment plan, and follow up if needed.
  29. The patient can proceed to the register for payment for the visit and rx, if prescribed.
  30. If the patient requests written results, the **POC Test Results Form** should be filled out and provided.
  31. File the completed **Intake Form and Assessment Form** in the POCT file folder and keep in the pharmacy for a minimum of 2 years. Prescriptions should be filed with all other prescriptions in the pharmacy.
  32. If the patient is user BCBS, bill for the visit and test.
  33. Positive influenza cases that result in hospitalization or death are required to be reported to the Arkansas Department of Health (ADH) at <https://flureport.adh.arkansas.gov>. To aid in influenza surveillance, ADH also encourages providers to report other positive influenza test results to the same website.
    - Create an account using your name and organization name, which is Harps Pharmacy + your store number
    - Save the URL to your browser favorites for quick access

# Influenza Treatment Protocol

## I. Purpose

The purpose of this standing order is to reduce morbidity and mortality of influenza infection in Arkansas by allowing Arkansas-licensed pharmacists to initiate therapy including ordering and/or dispensing treatment medications, along with any necessary supplies for administration, to eligible persons who are influenza positive or who have household exposure.

## II. Authority

This standing order is issued pursuant to Act 503 of 2021 (HB 1246) (Arkansas Code § 17-92-101) to authorize licensed pharmacists in Arkansas to order and/or dispense influenza treatment medications according to the provisions of Arkansas Code § 17-92-101 and the requirements of this standing order.

## III. Screening and Assessment

The Board of Pharmacy will adopt screening assessment and questionnaire (Appendix A) to be used by pharmacists throughout the state. When a patient requests point-of-care testing services, or when a pharmacist, in his or her professional judgement, decides to initiate point-of-care testing and treatment, the patient will be assessed for presenting signs and symptoms that warrant influenza testing, parental consent for individuals under the age of 18, and if appropriate, administer a rapid influenza point-of-care test.

## IV. Dispensing Guidelines

### A. Eligibility Criteria

#### Inclusion:

- Age 3 years and older
- Reported symptoms or household exposure onset < 48 hours before time of presentation
- CLIA-waived point-of-care test for influenza virus is performed or household exposure

#### Exclusion:

- History of adverse reactions to any previous influenza treatment
- Pregnancy
- Use of antiviral therapy for influenza in the past **30 days**
- Flu-like symptoms for more than 48 hours
- Immunocompromised defined as:
  - Been receiving active cancer treatment for tumors or cancers of the blood

- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response
- Clinically unstable based on the clinical judgement of the pharmacist or any of the following criteria:
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
    - For age 3-9 years: Systolic blood pressure <70 + (age in years × 2)
  - Tachypnea (>25 breaths/min adult or >20 breaths/min <18 y/o)
  - Oxygen saturation (SpO<sub>2</sub>) <90% via pulse oximetry

## B. Contraindications

Do not administer oseltamivir to an individual with a known hypersensitivity to oseltamivir or any component of the formulation

Do not administer zanamivir to an individual with a known hypersensitivity to zanamivir or any component of the formulation (contains milk proteins)

Do not administer baloxavir to an individual with a known hypersensitivity (e.g., anaphylaxis, angioedema, urticaria, erythema multiforme) to baloxavir or any component of the formulation

## C. Product Availability

Influenza treatment products that may be dispensed/provided under this standing order. Following dosing below, pharmacist can dispense any commercial available product form (tablet, capsule, suspension) based on availability and patient preference.

### 1. Oral Oseltamivir dosing:

- **Adults, treatment:** 75 mg twice a day x 5 days
- **Adults, prophylaxis:** 75 mg once daily x 7 days if vaccinated, 14 days if unvaccinated
- **Children, treatment** Weight-based dosing x 5 days:
  - **15 kg or less:** 30 mg twice a day
  - **>15 to 23 kg:** 45 mg twice a day
  - **>23 to 40 kg:** 60 mg twice a day
  - **> 40 kg:** 75 mg twice a day

- **Children, prophylaxis:** Weight-based dosing x 7 days
    - **15 kg or less:** 30 mg once a day
    - **>15 to 23 kg:** 45 mg once a day
    - **>23 to 40 kg:** 60 mg once a day
    - **> 40 kg:** 75 mg once a day
2. Inhaled Zanamivir dosing:
- **Adults, treatment:** 10mg (two 5mg inhalations) twice a day x 5 days
  - **Adults, prophylaxis:** 10mg (two 5mg inhalations) once daily x 7 days
  - **Children, treatment (7 years or older):** 10mg (two 5mg inhalations) twice a day x 5 days
  - **Children, prophylaxis (5 years or older):** 10mg (two 5mg inhalations) once daily x 7 days
  -
3. Oral Baloxavir dosing:
- **Adults and Children 12 and older, treatment:**
    - **40 kg to less than 80kg:** single dose of 40 mg
    - **80 kg or more:** single dose of 80mg
  - **Adults, children 12 and older, prophylaxis**
    - **40 kg to less than 80kg:** single dose of 40 mg
    - **80 kg or more:** single dose of 80mg

#### D. Warnings/Precautions

1. Oseltamivir
- Disease-related concerns
    - Cardiovascular disease: Use with caution in patients with chronic cardiac disease
    - Hepatic impairment: Use with caution in patients with severe hepatic impairment
    - Renal impairment: Use with caution; dosage adjustment is required for patients with renal impairment. Not recommended for patients with end stage renal disease (ESRD) not undergoing dialysis
    - Respiratory disease: Use with caution in patients with respiratory disease
  - Dosage forms specific issues
    - Some dosage form may contain sodium benzoate/benzoic acid which are metabolites of benzyl alcohol and have been associated with a potentially fatal toxicity in neonate (“gasping syndrome”)
    - Oral suspension contains sorbitol (delivers ~2 g sorbitol per 75 mg dose) which is greater than the maximum daily limit for patients with hereditary fructose intolerance; may cause diarrhea and dyspepsia; use with caution
  - Appropriate Use

- Oseltamivir is not a substitute for the influenza virus vaccine. It has not been shown to prevent primary or concomitant bacterial infections that may occur with influenza virus. Antiviral treatment should begin within 48 hours of symptom onset; however, the CDC recommends that treatment may still be beneficial and should be started in patients with severe, complicated, or progressive illness, and in hospitalized patients if >48 hours. Treatment should not be delayed while awaiting results of laboratory tests for influenza. Outpatients who are not at high risk for developing severe or complicated illness are not likely to benefit if treatment is started >48 hours after symptom onset (CDC 2020a).

## 2. Zanamivir

- Concerns related to adverse effects
  - Allergic reactions: Allergic-like reactions, including anaphylaxis, oropharyngeal edema, and serious skin rashes have been reported. Discontinue use and institute appropriate treatment if an allergic reaction occurs.
  - Neuropsychiatric events: rare occurrences of neuropsychiatric events (including confusion, delirium, hallucinations, seizure, and/or self-injury) have been reported, primarily in pediatric patients; may be abrupt in onset. Direct causation is difficult to establish; influenza infection may also be associated with behavioral and neurologic changes.
  - Respiratory effects: Bronchospasm, including serious cases and some with fatal outcomes, and decreased lung function have been reported in patients with and without airway disease; discontinue with bronchospasm or decreased lung function. For a patient with an underlying airway disease where a medical decision has been made to use zanamivir, a fast-acting bronchodilator should be made available.
- Respiratory disease
  - Not recommended for use in patients with underlying respiratory disease, such as asthma or COPD, due to lack of efficacy in influenza treatment and risk of serious bronchospasm. If zanamivir is prescribed in such patients, closely monitor respiratory function.
- Nursing home patients
  - Nursing home patients: Effectiveness has not been established for prophylaxis of influenza in nursing home patients (per manufacturer); however, the CDC recommends zanamivir as an option to be used to control institutional outbreaks of influenza (refer to current guidelines) (CDC 2020a).

## 3. Baloxavir

- Bacterial infection
  - There is no evidence of efficacy of baloxavir marboxil in illnesses (eg, bacterial infections) caused by pathogens other than influenza viruses. Serious bacterial infections may begin with influenza-like symptoms, may

coexist with, or occur as an influenza complication. Baloxavir marboxil has not been shown to prevent such complications. Monitor for potential secondary bacterial infections and manage appropriately.

- Hypersensitivity
  - Hypersensitivity reactions, including anaphylaxis, angioedema, urticaria, and erythema multiforme have been reported; evaluate and treat accordingly.

#### **E. Documentation**

Positive influenza cases that result in hospitalization or death are required to be reported to the Arkansas Department of Health (ADH) at <https://flureport.adh.arkansas.gov>. To aid in influenza surveillance, ADH also encourages providers to report other positive influenza test results to the same website. Patient records must be furnished to a health care practitioner designated by the patient upon the request of the patient. Documentation may include, but is not limited to, presenting signs and symptoms that warrant influenza testing, parental consent for individuals under the age of 18, and results of RIDT. Maintain records of all patients receiving services for two (2) years.

## INTAKE FORM

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: *Influenza*

PATIENT INFORMATION		
Name:	Date of Birth:	Age:
Address:	City/State/Zip:	
Email Address:	Phone:	
Primary Care Provider:		
Medication allergies?		
Current medications? (prescription, over-the-counter, herbals, topical medications, pain or allergy medication, and any supplements/vitamins)		
Treatments tried for the current condition (if none please indicate N/A):		

PATIENT ELIGIBILITY		
1. Are you 3 years of age and older?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Are you pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Have you ever been diagnosed with a weakened immune system? (e.g. cancer, transplant, or long term steroids)	<input type="checkbox"/> Yes* <small>*Pharmacists see page 2, #4 for criteria</small>	<input type="checkbox"/> No
4. When did your flu-like symptoms <b>start</b> ?	<input type="checkbox"/> More than 2 days ago	<input type="checkbox"/> 2 days ago, yesterday or today
5. Do you have any of the following flu-like symptoms? (check all that apply)	<input type="checkbox"/> Fever <input type="checkbox"/> Nasal congestion <input type="checkbox"/> Muscle/body aches <input type="checkbox"/> Cough <input type="checkbox"/> Sore throat <input type="checkbox"/> Other: _____	
6. Do you have any of the following? (check all that apply)	<input type="checkbox"/> History of allergic reactions to influenza treatment <input type="checkbox"/> History of physiologic side effects from any previous influenza treatment <input type="checkbox"/> Use of antiviral therapy for influenza in the <b>past 30 days</b> <input type="checkbox"/> Received influenza (flu) vaccine within the past 12 months	

Consent and Waiver: I consent to the staff to administer Influenza A+B Fluorescent Immunoassay (FIA), I fully release and discharge Harps pharmacy, its affiliations, and their officers, and employees from any illness, injury, loss, or damage that may result there from. I consent the release of medical information when necessary for medical protocol or disease tracking purposes. I authorize and request payment of medical benefits directly to this provider. I agree that the authorization will cover all medical services rendered until I revoke the authorization. I agree to be charged the usual and customary charge for the provided service if coverage is denied, or any copay or deductible that results.

**Patient Signature (or Guardian if <18)** \_\_\_\_\_ **Date** \_\_\_\_\_

*When complete, please return the form to pharmacy staff along with insurance information*

## ASSESSMENT FORM FOR INFLUENZA-- FOR PHARMACY STAFF ONLY--

<b>Physical Assessment</b>	<b>REFER TO PCP</b> if determined clinically unstable or any of the following criteria
<input type="checkbox"/> Weight (in kg): _____ <input type="checkbox"/> Blood pressure: _____ <input type="checkbox"/> RR: _____ <input type="checkbox"/> %Oxygen: _____ <input type="checkbox"/> Temperature: _____	<input type="checkbox"/> Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg <input type="checkbox"/> For age 3-9 years: Systolic blood pressure < 70 + (age in years × 2) <input type="checkbox"/> Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o <input type="checkbox"/> Low oxygen <90% oxygen via pulse oximetry
<b>CLIA-waived POCT Result</b>	<input type="checkbox"/> Positive for influenza – continue <input type="checkbox"/> Negative for influenza – refer to PCP + Symptomatic Treatment OR household post-exposure prophylaxis

Pharmacist Interpretation of qualifying questions and physical assessment; refer to PCP as appropriate. Exclusion criteria does not preclude from testing services. **Refer to PCP for treatment if:**

- |   |                     |
|---|---------------------|
| 1. If patient is under 3 years of age   | <b>REFER TO PCP</b> |
| 2. If patient is pregnant   | <b>REFER TO PCP</b> |
| 3. If patient has had symptoms >48 hours  | <b>REFER TO PCP</b> |
| 4. If patient is immunocompromised  | <b>REFER TO PCP</b> |
| a. Been receiving active cancer treatment for tumors or cancers of the blood  |                     |
| b. Received an organ transplant and are taking medicine to suppress the immune system   |                     |
| c. Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system                               |                     |
| d. Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)  |                     |
| e. Advanced or untreated HIV infection  |                     |
| f. Active treatment with high-dose corticosteroids (20mg prednisone daily for >2 weeks) or other drugs that may suppress your immune response |                     |
| 5. If patient has history of adverse reactions to previous influenza treatment  | <b>REFER TO PCP</b> |
| 6. If patient has used antiviral agents for influenza in the past 30 days   | <b>REFER TO PCP</b> |

Treat using protocol if:

1. Age 3 years and older
2. Reported symptoms or household exposure onset < 48 hours before time of presentation
3. CLIA-waived point-of-care test for influenza virus is performed
  - a. Symptomatic patient is positive for influenza virus via CLIA-waived point-of-care test
4. Household post-exposure prophylaxis

Diagnosis of Patient		
<input type="checkbox"/> Influenza ADULT <input type="checkbox"/> Influenza Prophylaxis Adult	<input type="checkbox"/> Influenza CHILDREN and ADOLESCENTS <input type="checkbox"/> Influenza Prophylaxis CHILDREN and ADOLESCENTS	<input type="checkbox"/> Refer to PCP

\*the following can act as the prescription

ADULT Therapy Options		
<b>Influenza Adult Treatment</b>		
<input type="checkbox"/> Oseltamivir	Dispense: <input type="checkbox"/> 75mg #10 No refills	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
<input type="checkbox"/> Zanamivir	Dispense: <input type="checkbox"/> 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
<input type="checkbox"/> Baloxavir	Dispense: <input type="checkbox"/> 40mg x 1 (if ≥40kg to 79kg) <input type="checkbox"/> 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now
<b>Influenza Adult Prophylaxis</b>		
<input type="checkbox"/> Oseltamivir	Dispense: <input type="checkbox"/> 75mg #7 (if vaccinated) <input type="checkbox"/> 75mg #14 (if unvaccinated) No refills	Sig: Take 1 (one) (75mg) by mouth once daily x 7 days Sig: Take 1 tablet by mouth once daily x 14 days
<input type="checkbox"/> Zanamivir	Dispense: <input type="checkbox"/> 1 inhaler No refills	2 inhalations by mouth once daily x 7 days
<input type="checkbox"/> Baloxavir	Dispense: <input type="checkbox"/> 40mg x 1 (if ≥40kg to 79kg) <input type="checkbox"/> 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now

Patient: \_\_\_\_\_.

Prescribed by: \_\_\_\_\_.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_.

Follow-Up in 48 hours	
Assessment:	<input type="checkbox"/> If symptoms persist, refer to PCP

\*the following can act as the prescription

CHILDREN and ADOLESCENTS Therapy Options		
Influenza Children or Adolescent <b>Treatment</b>		
Weight (kg): _____		
<input type="checkbox"/> Oseltamivir	Dispense: Weight-based dosing <input type="checkbox"/> ≤15kg: 30mg #10 <input type="checkbox"/> >15-23kg: 45mg #10 <input type="checkbox"/> >23-40kg: 60mg #10 <input type="checkbox"/> >40kg: 75mg #10 No refills	Sigs: <input type="checkbox"/> ≤15kg: 30mg by mouth BID x 5 days <input type="checkbox"/> >15-23kg: 45 by mouth BID x 5 days <input type="checkbox"/> >23-40kg: 60mg by mouth BID x 5 days <input type="checkbox"/> >40kg: 75mg by mouth BID x 5 days
<input type="checkbox"/> Zanamivir	Dispense: <input type="checkbox"/> 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
<input type="checkbox"/> Baloxavir	Dispense: <input type="checkbox"/> 40mg x 1 <input type="checkbox"/> 80mg x 1 No refills	Take 1 tablet by mouth now
Influenza Children or Adolescent <b>Prophylaxis</b>		
Weight (kg): _____		
<input type="checkbox"/> Oseltamivir	Dispense: Weight-based dosing <input type="checkbox"/> ≤15kg: 30mg #7 <input type="checkbox"/> 15-23kg: 45mg #7 <input type="checkbox"/> 23-40kg: 60mg #7 <input type="checkbox"/> >40kg: 75mg #7 No refills	Sigs: <input type="checkbox"/> ≤15kg: 30mg by mouth daily x 5 days <input type="checkbox"/> 15-23kg: 45 by mouth daily x 5 days <input type="checkbox"/> 23-40kg: 60mg by mouth daily x 5 days <input type="checkbox"/> >40kg: 75mg by mouth daily x 5 days
<input type="checkbox"/> Zanamivir	Dispense: <input type="checkbox"/> 1 inhaler No refills	2 inhalations by mouth once daily x 7 days
<input type="checkbox"/> Baloxavir	Dispense: <input type="checkbox"/> 40mg x 1 (if ≥40kg to 79kg) <input type="checkbox"/> 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now

Patient: \_\_\_\_\_

Prescribed by: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Follow-Up in 48 hours	
Assessment:	<input type="checkbox"/> If symptoms persist, refer to PCP

**References:**

Infectious Diseases Society of America. Influenza Guidelines. <http://www.idsociety.org>  
 LexiComp. Wolters Kluwer Clinical Drug Information. <http://online.lexi.com>

## Influenza Recommendations

### Positive Result:

- If you are sick with the flu, stay home and avoid contact with others except for medical care.
- People are most contagious in the first 3 to 4 days after their symptoms begin. Symptoms generally begin between 1 to 4 days after a person has been exposed to the flu.
- Most people have mild illness. If you are in a high risk group (young children, people 65 and older, pregnant people and people with certain medical conditions) you are at increased risk of flu-related complications and should receive antiviral treatment.
- You should stay home for at least 24 hours after your fever is gone (without the need to use a fever reducing medication).
- If you must leave home, wear a facemask or cover coughs and sneezes with a tissue. If you do not have a tissue cough or sneeze into your elbow, not your hands.
- Wash your hands often to keep from spreading the flu.
- You should NOT give children or teenagers who have the flu aspirin or any other salicylate containing product (Pepto Bismol). This can cause a rare complication called Reye's Syndrome.
- When treatment is started within 1 to 2 days after symptoms begin, antiviral drugs can lessen symptoms and shorten the amount of time you are sick. Options include: Tamiflu, Relenza, and Xofluza.

Look for **emergency warning signs** for the flu. If someone is showing any of these signs, **seek emergency medical care immediately**:

- Adults: Trouble breathing, Persistent pain or pressure in the chest, persistent dizziness, seizures, unable to urinate, severe muscle pain, severe weakness, fever or cough that improve but then worsen, worsening of chronic medical conditions
- Children: Fast or trouble breathing, bluish lips or face, ribs pulling in with each breath, chest pain, severe muscle pain, dehydration (no urine for 8 hours, dry mouth, no tears when crying), not alert, seizures, fever above 104 ° F, fever or cough that improve but then worsen, worsening of chronic medical conditions

### Negative Result:

This cannot rule out the flu or other illness. If symptoms continue or worsen, follow up with a healthcare provider is warranted.

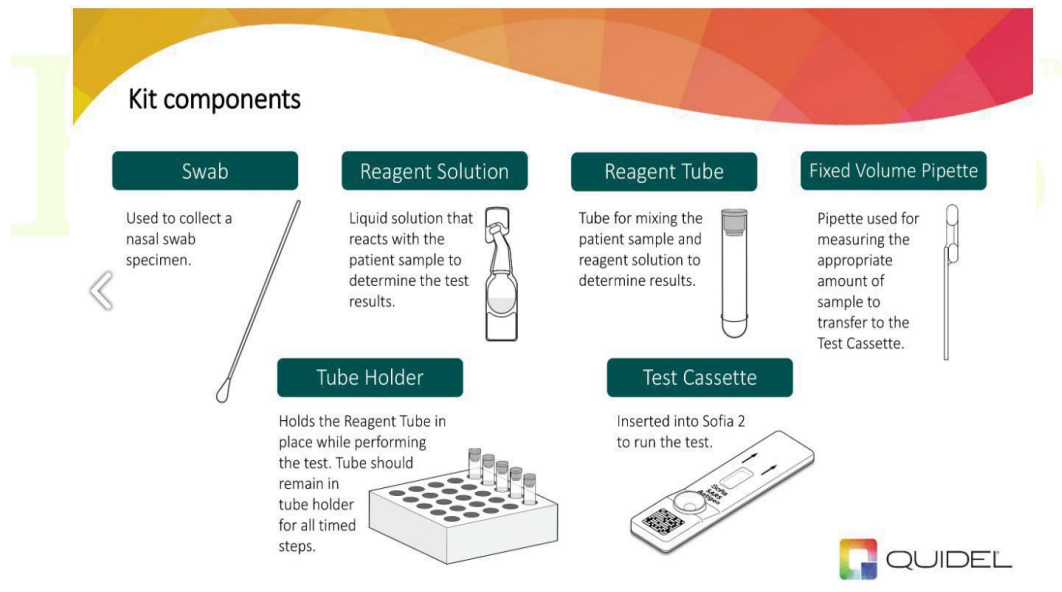
### Know the difference:

Flu symptoms	Cold Symptoms
<ul style="list-style-type: none"> <li>• Abrupt onset</li> <li>• Fever and headache are common</li> <li>• Usual aches, fatigue, or weakness</li> <li>• Chills</li> <li>• Sneezing occurs sometimes</li> <li>• Chest discomfort or cough</li> <li>• Stuffy nose or sore throat occurs sometimes</li> </ul>	<ul style="list-style-type: none"> <li>• Gradual onset</li> <li>• Fever or headache is rare</li> <li>• Slight aches, sometimes fatigue or weakness</li> <li>• Chills are uncommon</li> <li>• Sneezing</li> <li>• Mild to moderate chest discomfort or cough</li> <li>• Stuffy nose and sore throat</li> </ul>

# COVID

## Prior to Patient Appointment

1. If you are scheduling an appointment for the patient, enter the patient information into CareScheduler, including **medical** insurance info, if necessary. Inform the patient to bring their insurance card to the appointment as well.
  - Insurance Name
  - ID
  - Medical Group
  - Is the patient the policy holder? If no:
    - a) Policy holder's name, DOB, and Address (if different than patient's address)
2. If the patient has BCBS medical insurance, login to Availity to check for patient's copay/deductible/coinsurance-- see Availity Training document for instructions.
  - *It is not necessary to check this while on the phone with the patient, unless they request it. You may look this up after you schedule the appointment and have that information ready when the patient arrives.*
3. If the patient is paying cash, refer to the **POCT Pricing Guide for Cash Pay Patients** and notify the patient of the cost.
4. Ensure the clinical area is clean and prepared for the appointment with necessary testing supplies.



Patient Arrival

5. The technician will take out the **Intake and Assessment Form (COVID)** for the patient to complete.
6. If patient has BCBS, technician will make a copy of their insurance card.
  - If you did not previously check Eligibility and Benefits in Availity, login to determine if a copay or deductible amount is due.
7. After completion of the form, inform the patient we will let them know when we are ready for them.
8. The technician will prepare the testing area with supplies (if not prepared before patient arrival) for the assessment and testing, and don Personal Protective Equipment (PPE). A mask and gloves, at minimum, should be worn.
  - *NOTE: The reagent solution should not be added to the reagent tube until it is determined the patient is clinically stable and will be tested.*
9. Simultaneously, the pharmacist will determine, based on the patient answers from the Intake Form, if they meet eligibility criteria below:
  - **Age 3 and over**
  - **If testing for exposure, >5 days post exposure is necessary to produce a reliable result.**

Patient Assessment

10. If the patient is eligible, the technician will take the patient to the assessment and testing area and collect vital signs on the **Intake and Assessment Form**.
  - Gather vital signs (Blood pressure, RR, %Oxygen, and Temp)
11. After the vital signs are complete, the technician will bring the form to the Pharmacist who will determine if the patient meets clinical stability guidelines. Pharmacist will refer to PCP if clinically unstable.

Physical Assessment	REFER TO PCP if determined clinically unstable or any of the following criteria
<input type="checkbox"/> Blood pressure: _____	<input type="checkbox"/> Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
<input type="checkbox"/> RR: _____	<input type="checkbox"/> For age 3-9 years: Systolic blood pressure < 70 + (age in years × 2)
<input type="checkbox"/> %Oxygen: _____	<input type="checkbox"/> Tachypnea >25 breaths/min adult or >20 breaths/min <18 y/o
<input type="checkbox"/> Temperature: _____	<input type="checkbox"/> Low oxygen <90% oxygen via pulse oximetry

12. Once the Pharmacist has reviewed the patient information, they will proceed to the testing area to assess the patient, utilizing the Assessment Form.
  - Assessing the patient for COVID should include a minimum of:
    - The patient’s current signs and symptoms
    - When signs/symptoms began
    - Any known exposure to a person with illness
    - Vaccination status

Sample Collection

13. Once it has been determined the patient will be tested, the technician will come back to perform the test.
14. Add the reagent solution to the tube. **Swirl the Reagent Tube to dissolve its contents.**
15. We will be performing a **nasal swab** sample using the nasal swab supplied in the kit. Prior to collecting the nasal swab, the patient should be instructed to blow their nose. To collect a direct anterior nasal swab sample, carefully insert the swab (provided in the kit) into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.

- **NOTE: this is a nasal swab only. It is not necessary to perform a nasopharyngeal collection.**
- 16. Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.
- 17. Provide the patient a copy of the **COVID Recommendations** handout.
- 18. The patient can then be instructed to proceed to the pharmacy register for payment. They may wait near the pharmacy for results or they can wait in their car and we will call them.
- 19. Leave the Swab in the Reagent Tube for **1 minute**, then proceed to run the test on Sofia 2.

### Test Procedure

- 20. Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in your biohazard waste.
- 21. Fill the provided Small, Clear 120 µL Fixed Volume Pipette with the patient sample from the Reagent Tube.
  - To fill the Fixed Volume Pipette with the patient sample:
    - **FIRMLY** squeeze the top bulb.
    - Still squeezing, place the Pipette tip into the patient sample.
    - With the Pipette tip still in the patient sample, slowly release pressure on bulb to fill the Pipette.
- 22. Firmly squeeze the top bulb to empty the contents of the Small, Clear 120 µL Fixed Volume Pipette into the Test Cassette sample well. Extra liquid left over in the overflow bulb should be left behind.
  - **NOTE:** The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample. Discard the pipette in your biohazard waste.
  - Promptly proceed to the next section, Using Sofia 2, to complete the test.

### Using Sofia 2

- 23. Manually input the **User ID (1234)** using the on-screen keypad.
- 24. Verify that Sofia 2 is set to the desired mode: WALK AWAY or READ NOW
  - WALK AWAY Mode (utilize when 1 test is being performed)
    - In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time.
  - READ NOW Mode (utilize if multiple tests are being performed)
    - **Critically important:** Allow the test to develop for the **FULL 15 minutes** BEFORE placing it into Sofia 2.
    - The user must first place the Test Cassette onto the counter for 15 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute.
- 25. Open the Sofia 2 drawer. Insert the prepared Test Cassette into the drawer of Sofia 2 and close the drawer. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen in 15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute.
- 26. In walk away mode, the tech should set a timer in the pharmacy to alert when results should be available.

## Interpret Results/Prescribe Treatment

27. After a maximum of 15 minutes, Sofia 2 will display the results. The pharmacist will read the results and complete the results section of the **Intake and Assessment Form (COVID)**.
  - An invalid result will appear as an X and the test will need to be performed again with a new patient sample and a new test cassette.
  - Recommended symptomatic treatment should be given for a positive or negative result, as well as when to follow up with a HCP if symptoms do not improve.
28. Notify the patient of results and recommend symptomatic treatment, if needed.
29. If the patient has requested written results, the **POC Test Results Form** should be filled out and provided.
30. Record the test results at <https://covid19reportingtool.adh.arkansas.gov/> within 24 hours of testing.
  - Username: HarpsFood Password: German1120dj
31. File the completed **Intake and Assessment Form (COVID)** in the POCT file folder and keep in the pharmacy for a minimum of 2 years.
32. If the patient has BCBS, bill for the visit and test.

# Intake and Assessment Form

## COVID-19 Point of Care Testing

### Patient Information

Name \_\_\_\_\_ DOB \_\_\_\_\_ Age \_\_\_\_\_ Gender \_\_\_\_\_  
 Address \_\_\_\_\_ City/State/Zip \_\_\_\_\_  
 Phone \_\_\_\_\_ Primary Care Physician \_\_\_\_\_

Do you have any symptoms? -If yes, please describe: _____	<input type="radio"/> Yes	<input type="radio"/> No
Have you had direct exposure to someone positive for COVID-19 in the last 14 days? -Waiting a minimum of 5 days post exposure to test will provide a more reliable result	<input type="radio"/> Yes	<input type="radio"/> No

### Insurance Information

Insurance Name \_\_\_\_\_ ID \_\_\_\_\_ Group \_\_\_\_\_  
 Relationship to Insured \_\_\_\_\_

#### Subscriber/Insured Information (if different than patient)

First Name \_\_\_\_\_ Last Name \_\_\_\_\_ DOB \_\_\_\_\_  
 Address \_\_\_\_\_ City/State/Zip \_\_\_\_\_

### Payment (Cash pay)

Card Type \_\_\_\_\_ Number \_\_\_\_\_ Exp \_\_\_\_\_ CCV \_\_\_\_\_

**Consent and Waiver:** I consent to the staff to administer the SARS-CoV-2 (COVID-19) antigen test. I fully release and discharge Harps pharmacy, its affiliations, and their officers, and employees from any illness, injury, loss, or damage that may result there from. I consent the release of medical information when necessary for medical protocol or disease tracking purposes. I authorize and request payment of medical benefits directly to this COVID-19 provider. I agree that the authorization will cover all medical services rendered until I revoke the authorization. I agree to be charged the usual and customary charge for the provided service if coverage is denied, or any copay or deductible that results.

**Patient (or Guardian) Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

### Pharmacy Use Only

Physical Assessment	Refer to PCP if determined clinically unstable or any of the following criteria
<ul style="list-style-type: none"> <li><input type="radio"/> Blood pressure: _____</li> <li><input type="radio"/> RR: _____</li> <li><input type="radio"/> %Oxygen _____</li> <li><input type="radio"/> Temperature _____</li> </ul>	<ul style="list-style-type: none"> <li><input type="radio"/> Systolic blood pressure &lt;90 or diastolic &lt;60                             <ul style="list-style-type: none"> <li><input type="radio"/> For age 3-9 years: Systolic &lt;70 + (age in years x2)</li> </ul> </li> <li><input type="radio"/> Tachypnea &gt;25 breaths/min adult or &gt;20 breaths/min &lt;18 y/o</li> <li><input type="radio"/> Low oxygen &lt;90% oxygen via pulse oximetry</li> </ul>

**POC Test Result**      **COVID-19**       **Positive**       **Negative**

Pharmacist Signature \_\_\_\_\_ Date \_\_\_\_\_

NPI \_\_\_\_\_ Store # \_\_\_\_\_

**Positive Result:**

- Stay home for at least 5 days and isolate from others in your home.
- Wear a well-fitted mask if you must be around others in your home.
- You may end isolation after 5 full days if you are fever-free for 24 hours (without use of fever-reducing medication) and your symptoms are improving.
  - If you did NOT have symptoms, you may end isolation after 5 full days after your positive test.
  - *NOTE: Day 0 is your first day of symptoms or a positive viral test. Day 1 is the first full day after your symptoms developed or your test specimen was collected.*
- If you were severely ill with COVID-19, you should isolate for at least 10 days and consult your doctor before ending isolation.
- Wear a mask for 10 full days any time you are around others inside your home or in public. Do not go places where you are unable to wear a mask.
- Avoid travel.
- Avoid being around people who are at risk.
- After you have ended isolation, if your COVID-19 symptoms worsen, restart your isolation at day 0. Antiviral drugs are a treatment option. There are three: Paxlovid, Veklury, and Lagevrio.

Look for **emergency warning signs** for COVID-19. If someone is showing any of these signs, **seek emergency medical care immediately:**

- Trouble breathing, persistent pain or pressure in the chest, new confusion, inability to wake or stay awake, bluish lips or face

**Negative Result:**

This cannot rule out COVID-19 or other illness. If symptoms continue or worsen, follow up with a healthcare provider is warranted.

**Quarantine**

If you were exposed to someone with COVID-19, follow these guidelines:

You are not up-to-date on COVID-19 vaccinations:	You are up to date on COVID-19 vaccinations or had confirmed COVID-19 within the past 90 days:
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<p>Stay home and <a href="#">quarantine</a> for at least 5 full days. Wear a well-fitted mask if you must be around others in your home.</p> <p>Even if you don't develop symptoms, get tested at least 5 days after you last had close contact.</p> <p><b>Watch for symptoms</b></p> <p>Watch for symptoms until 10 days after you last had close contact with someone with COVID-19.</p> <p><b>If you develop symptoms</b></p> <p><a href="#">Isolate</a> immediately and get tested. Continue to stay home until you know the results. Wear a well-fitted mask around others.</p>	<p>You do not need to stay home unless you develop symptoms.</p> <p>Even if you don't develop symptoms, get tested at least 5 days after you last had close contact.</p> <p><b>Watch for symptoms</b></p> <p>Watch for symptoms until 10 days after you last had close contact with someone with COVID-19.</p> <p><b>If you develop symptoms</b></p> <p><a href="#">Isolate</a> immediately and get tested. Continue to stay home until you know the results. Wear a well-fitted mask around others.</p>
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*All information obtained from the Centers for Disease Control and Prevention. Visit [cdc.gov/coronavirus](https://cdc.gov/coronavirus).*

### POCT Pricing Guide for Cash Pay Patients

<b><i>Strep</i></b>	Assessment + Test	\$94
	Assessment Only (Center Score <2)	\$70
<b><i>Flu</i></b>	Assessment + Test	\$94
	Assessment for Prophylaxis	\$70
<b><i>COVID</i></b>	Assessment + Test	\$94
	Any Additional Test	\$24

# Guide to Billing POCT Medical Claims

Medical billing for Point of Care services involves multiple codes per claim:

Evaluation and Management Code + CPT Code + Diagnosis Code

## 1. Evaluation and Management code (E/M code)

Evaluation and Management Codes			
New patient codes	Total time range	Established patient codes	Total time range
		<b>99211</b>	<10 mins
<b>99202</b>	15-29 mins	<b>99212</b>	10-19 mins
<b>99203</b>	30-44 mins	<b>99213</b>	20-29 mins

- a. This is a time-based billing code that pays for pharmacist time.
- b. Activities that are included in billable time include:
  - i. preparing to see the patient (eg, review of tests)
  - ii. obtaining and/or reviewing separately obtained history
  - iii. performing a medically appropriate examination and/or evaluation
  - iv. counseling and educating the patient/family/caregiver
  - v. ordering medications, tests, or procedures
  - vi. referring and communicating with other health care professionals (when not separately reported)
  - vii. documenting clinical information in the electronic or other health record
  - viii. independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
  - ix. care coordination (not separately reported)
- c. These activities CANNOT be counted as billable time:
  - i. travel
  - ii. the performance of other services that are reported separately (Labs)
  - iii. teaching that is general and not limited to discussion that is required for the management of a specific patient
  - iv. *time spent with technician*
- d. Determination between a “New” patient and “Established patient” is as follows:
  - i. A **new patient** is one who has not received any professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.
    - o This is any patient who has not been seen for Point of Care services at your pharmacy in the past 3 years.
  - ii. An **established patient** is one who has received professional services from the physician or other qualified health care professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.

## 2. CPT/HCPCS code

- a. These codes are used to describe the evaluations, counseling, and/or laboratory test performed during the patient's visit, are usually 5 characters long, and include only alpha-numeric characters
- b. Modifiers: Two-character appendages added to CPT codes when additional information is needed for appropriate claims processing and payment. \*These are not always required\*

Point of Care Test	CPT Code	Modifier
Strep	87430	QW*
Flu (a/b)	87400	QW* 59**
COVID	87426	QW*

99\*QW modifier is added if billing Medicare or Medicaid

\*\*59 is added if billing 87400 twice, once for flu A and once for flu B.

### Important Points

- a. Sofia 2 influenza test DOES test for both A and B, so the 87400 CPT code will need to be processed twice, with 59 added as a Modifier to the second claim.
  - i. In order to do this, you will have to separately bill the two claims through Enterprise. Add 59 to the second 87400 claim. \*See billing example on page 53\*
- b. NOTE: Billing insurance for COVID testing is only permitted if the patient has exposure or symptoms. Testing for travel cannot be billed to insurance.

## 3. Diagnosis/symptom code

- a. Alpha-numeric diagnosis codes 3-7 characters long, used to describe the reason for the visit, counseling and/or laboratory test performed: i.e., what symptom(s) caused the patient to be concerned. These begin with a letter and usually contain a (.) after the first 3 characters.
- b. For a positive test, the diagnosis code is simply the positive result. **For a negative test, you will submit the primary symptom of the patient.**
  - i. Positive Strep Test = B95.0
  - ii. Negative Strep Test = R07.0 (or the appropriate primary symptom)
- c. Our most commonly used diagnosis codes will be:

ICD 10	Code description
B34.2	Coronavirus infection, unspecified
B34.9	Viral infection, unspecified
B95.0	Streptococcus, staphylococcus, group A
B95.1	Streptococcus, staphylococcus, group B
B98.5	Unspecified Streptococcus
B95.8	Unspecified Staphylococcus
B97.21	SARS- associated coronavirus, as the cause of diseases classified elsewhere
B97.29	Other coronavirus as the cause of diseases classified elsewhere
J11.1	Influenza due to unidentifed influenza virus, with other respiratory manifestations (includes influenza NOS)
J41.0	Smoker's cough
R05.9	Cough, unspecified
R07.0	Pain in throat
R07.1	Chest pain on breathing (painful respiration)
R09.81	Nasal congestion
R09.82	Postnasal Drip
R09.89	Runny nose
R10.9	Abdominal pain
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.2	Nausea with vomiting, unspecified
R50.9	Fever, unspecified
R51	Headache
R52	Generalized pain
R53.81	Malaise
R53.83	Fatigue
R82.90	Unspecified abnormal finding in urine
U07.1	COVID-19
Z30.09	Encounter for other general counseling and advice on contraception
Z32.00	Encounter for pregnancy test, result unknown
Z32.02	Encounter for pregnancy test, result negative
Z71.6	Tobacco abuse counseling
Z71.85	Encounter for immunization safety counseling
	Other specified counseling
Z71.89	Counseling; <b>Pregnancy prevention</b> ; Injury prevention counseling done; Life circumstance problem; <b>Medication counseling</b> ; Case/care management, sleep disorder; Case/care management, stroke; Case/care mgmt, CHF; Case/care management, diabetes ; Adjustment to life threatening illness; Alcohol prevention counseling; Asthma action plan; Asthma care coordination; <b>Asthma education</b> ; Asthma home management plan counseling; Breast feeding counseling; Care management; Coordination of asthma care; Counseling about accutane; Weight loss counseling; Women's Issues
Z71.9	Counseling, unspecified

## POCT Billing Example Case

A new patient presents to the pharmacy with a fever and body aches. After determining their eligibility for testing and treating, and evaluating for clinical stability, it is decided to test for influenza. You follow the Influenza Test and Treat protocol and swab the patient. The results are positive. You prescribe the patient Tamiflu, fill the prescription, and counsel. You now need to bill the encounter.

Step 1: Enter patient demographic information into Enterprise Rx.

Step 2: Enter Third Party information.

- **For BCBS patients, enter:**
  - **Bin: 016904**
  - **PCN: SB520**
  - ID: Full alpha-numeric ID on patient's card
  - Group: Medical Group on patient's card

Step 3: Scan the prescription, which should have the appropriate codes listed.

Step 4: Enter the Pharmacist who provided the service as the provider.

Step 5: Search product by typing "CPT + 5 digit code" and select the correct CPT code

- **NOTE:** The "Distributor" column is a description of the type of code you are billing (i.e., Influenza Test)

Show Expanded Search Criteria											
Search Local Search Corporate											
	Name	Strength	NDC Number	Pack	Distributor	OB	Avail...	Obs ...	Deactivat...	Specialty I...	Product...
1	CPT CODE 81025	81025 U	99999-9810-25	1 EA	URINE PREG TEST	0.0					
2	CPT CODE 87400	87400 U	99999-9874-00	1 EA	INFLUENZA TEST	-2.0					
3	CPT CODE 87426	87426 U	99999-9874-26	1 EA	COVID TEST	0.0					
4	CPT CODE 87430	87430 U	99999-9874-30	1 EA	STREP TEST	0.0					
5	CPT CODE 99202	99202 U	99999-9992-02	1 EA	NEW PT 15-29 M	0.0					
6	CPT CODE 99203	99203 U	99999-9992-03	1 EA	NEW PT 30-44 M	0.0					
7	CPT CODE 99211	99211 U	99999-9999-11	1 EA	EST PT <10 MIN	0.0					
8	CPT CODE 99212	99212 U	99999-9992-12	1 EA	EST PT 10-19 M	0.0					
9	CPT CODE 99213	99213 U	99999-9992-13	1 EA	EST PT 20-29 M	0.0					
0	CPT CODE 99406	99406 U	99999-9994-06	1 EA	SMK CESS 3-10 M	0.0					
	CPT CODE 99407	99407 U	99999-9994-07	1 EA	SMOK CESS >10 M	0.0					

Step 6: Proceed with Data Entry:

- Written date: Appointment/Test date
- Sig: Enter the code description (Influenza Test)
- Written/Dispense quantity = 1
- No refills
- Day supply = 1
- Select the correct Third Party (Transact Rx BCBS)
  - In Additional information, scroll to Claim Field:
    - In the **Product/Service ID Qualifier** line, enter:
      - ❖ 07 = Common Procedure Terminology (CPT4)
    - In the **Product/Service ID** line, enter:
      - ❖ the CPT code

Claim		
Product/Service ID Qualifier (436-E1)	None	07 = Common Procedure Terminology (CPT4)
Product/Service ID (407-D7)	None	87400
Procedure Modifier Code		Edit
Procedure Modifier Code (459-ER)	None	59

- Scroll to Clinical Field:
  - In the **Diagnosis Code Qualifier** line, enter:
    - ❖ 02 = International Classification of Diseases-10-Clinical Modifications (ICD-10-CM)
  - In the **Diagnosis Code** line, enter:
    - ❖ The Diagnosis Code that is most appropriate

Clinical		
Diagnosis Code		Edit
Diagnosis Code Qualifier (492-WE)	None	02 = International Classification of Diseases-10-Clinical Modifications (ICD-10-CM)
Diagnosis Code (424-D0)	None	J11.1

Step 7: Process through Product Dispensing.

- If you receive a rejection for Pharmacist NPI, enter 9999 into the PA number field in Additional Information to override.

Step 8: Process through Verification.

- The pharmacist should verify that the correct code is being billed for the correct patient on the correct date.

Step 9: Process through to Release to Patient Release and sign **POC** on the patient signature line to release.

Step 10: File the hardcopy with all other prescriptions.







Patient Name \_\_\_\_\_ DOB \_\_\_\_\_

**Results**

**Covid-19**

Positive  
 Negative  
 Test not performed

**Influenza**

Positive  
 Negative  
 Test not performed

**Strep**

Positive  
 Negative  
 Test not performed

Pharmacist Signature \_\_\_\_\_

License Number \_\_\_\_\_

National Provider Identifier (NPI) \_\_\_\_\_

Store Address \_\_\_\_\_

CLIA waiver ID # \_\_\_\_\_

Time \_\_\_\_\_

Date \_\_\_\_\_