Template Point-of-Care Testing and Treatment Policy and Procedures

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Acknowledgements: East Gate Pharmacy, CDC Ready?Set?Test!, Johns Hopkins

1. **Description**

   This policy will be used to outline the process related to point-of-care testing and treatment.

2. **Rationale**

   This policy will ensure the proper screening and management of [influenza, pharyngitis, COVID-19] at [Pharmacy] to include screening, provider recommendation, and follow-up.

3. **Evaluation of Results of Rapid Antigen Testing**

   Evaluating the results of a rapid antigen test should take into account the performance characteristics (e.g. sensitivity, specificity), instructions for use of the FDA-authorized assay, the prevalence of infection in that particular community (positivity rate over the previous 7–10 days or cases per population), and the clinical and epidemiological context of the person who has been tested. The evaluation of a diagnostic antigen test result should consider the length of time the patient has experienced symptoms. Generally, clinicians can rely upon a positive diagnostic antigen test result because the specificity of current FDA-authorized antigen tests is high. The sensitivity of current FDA-authorized antigen tests varies, and thus negative diagnostic testing results should be handled differently depending on the testing device and its stated performance characteristics. In most cases, negative antigen diagnostic test results are considered presumptive.

4. **Responsibilities**
   a. Point-of-Care Testing Coordinator: ____
      i. Responsible for technical oversight of all testing performed at the point-of-care
      ii. Established a training and competency program appropriate for the tests performed and the staff performing testing
      iii. Responsible for the test procedures and development any needed log sheets
      iv. Ensures that all point-of-care testing sites are performing testing according to written procedures, and are in compliance with all federal, state, and accreditation requirements.
   b. Site Medical Director: ____
      i. Ensures competent testing personnel with credentials that meet CLIA and state regulations
      ii. Ensures documentation of initial training and continuing education of testing personnel
      iii. Communicates and consults with Site Coordinator and testing personnel on a regular basis.
   c. Testing Personnel
      i. Responsible for specimen processing, test performance, result reporting according to laboratory guidelines and procedures
      ii. Only testing personnel who have completed a defined training program and can demonstrate competence will perform [influenza, pharyngitis, other] testing
      iii. Properly performs Quality Control and patient testing
      iv. Properly stores test kits and quality control solutions
      v. Documents all Quality Control results (both acceptable and failed QC), date, time, lot numbers, expiration dates, internal procedural control results, problems and corrective actions
      vi. Maintains a log of patient test results
      vii. Ensures test results are documented and communicated to patient

5. **Training**

   Training must be documented for each testing personnel using a [training checklist]. Training should occur for each personnel before the individual performs POCT without assistance for the first time, when procedures or test systems change, and every [year]. Training at a minimum includes:

a. Reading the manufacturer's instructions for performing the test
b. Observing a trained individual performing the test or viewing a video of a trained individual performing the test
c. Practicing the performance of the test with positive and negative controls
d. Practicing the specimen collection procedure(s)
e. Reviewing the procedures and forms on how to document the testing

6. **Pharmacy Site Requirements**
   a. The testing area should be a separate area where equipment and supplies along with the testing equipment will be located.
   b. A copy of the manufacturer's instructions will be kept on hand for easy reference
   c. The testing area is to be maintained in a state of cleanliness, order and efficiency in a manner conducive to productivity.
   d. Ambient temperature and humidity must be controlled during all seasons to minimize effects on reagents and test systems.
   e. Storage must be convenient to the testing area, sufficient for operational need and provide an environment which is appropriate for all stored materials.
   f. Patients are not permitted in the testing area.
   g. Workspace area where testing is performed should be level.
   h. Adequate lighting is required in the workspace area where test results are read and interpreted
   i. Equipment will be regularly cleaned by testing personnel as per manufacturer's recommendations.

7. **Quality Control**
   a. Routine quality control performance must be at least as frequent as the manufacturer's specifications.
      i. Types of control
         1. Internal controls evaluate whether the test is working as it should, enough sample is added, the sample is moving through the test strip correctly, and the electronic functions are working correctly.
         2. External controls evaluate whether the entire testing process is performed correctly and the control results are in the expected ranges or values as found in the manufacturer's instructions.
   b. Control material should monitor both the normal and abnormal ranges and correlate with the specimen matrix.
   c. All records of preventive maintenance and calibration checks will be documented in an [Equipment Maintenance Log Book] or equivalent.
   d. Equipment monitoring records are periodically reviewed, dated and signed by the Site Coordinator and POCT Coordinator
   e. All new lot numbers or shipments of reagent or controls are to be validated prior to being placed into service for patient testing
   f. Reagent and control shelf life shall be strictly observed

8. **Record keeping**
   a. Document all steps of the testing process to assure quality testing. All equipment logs, maintenance records, testing records, and test results should be kept for easy retrieval of information. The POCT Coordinator must periodically review records.
   b. 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.
   c. 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, pharyngitis] 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.

9. Order of Operations

a. Patient appointments. All POCT will be scheduled online at our website. We [do/do not] allow walk-ins. Patient appointment includes: day/time of appointment, type of testing requested, current signs and symptoms, patient eligibility questions, vaccination status, consent to test, and payment.

b. Patient Arrival
   i. Patients will remain in their vehicle and call the testing line indicated on their appointment confirmation to notify the staff of their arrival.
   ii. If influenza or pharyngitis, patient will be instructed to enter the clinic area for evaluation and testing.
   iii. If COVID-19 testing, patient will be instructed to remain in their vehicle and a testing personnel will go to their vehicle.

c. Patient screening and assessment for influenza or pharyngitis
   i. Testing personnel will complete the patient demographics and eligibility form (see appendix)
   ii. Testing personnel will collect patient's vitals
   iii. Testing personnel will collect patient sample for testing
   iv. Assessment of patient's clinical status and interpretation and discussion of results will be performed by a pharmacist.

d. Sample Collection
   i. Obtain the appropriate patient test by verifying the patient name and date of birth
   ii. Must follow manufacturer's instruction for sample collection
   iii. The collected sample will be placed in a sample test tube for transport to the testing area or directly placed with testing reagent.

e. Testing the sample
   i. Samples will be tested according to the package insert.
   ii. It is important to have a timer with an alarm function on hand to time the sample as the results do not remain on the screen indefinitely once the test is completed.

f. Documenting results
   i. All patient samples will be recorded in a test log with date, patient, sample #, test type, results, testing personnel initials

g. Patient Notification
   i. For COVID-19, patient's will be called within 2 hours of testing with their result. A copy will also be emailed to the patient.
   ii. For influenza or pharyngitis testing, patient will remain at the clinic location for their results. Pharmacist will review the result with the patient and recommend appropriate OTC and/or Rx options, per Arkansas state protocol.

h. Influenza and Pharyngitis Treatment
   i. Pharmacist will complete protocol form with patient eligibility, symptoms, and result of POCT. (see appendix)
   ii. Pharmacist will prescribe using the treatment protocol if appropriate.
   iii. Treatment will be dispensed and patient counseled on medication and management of infection.

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

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

-- FOR PHARMACY STAFF ONLY--

Physical Assessment	**REFER TO PCP** if determined clinically unstable or any of the following criteria
❑ Blood pressure:___________________ ❑ RR:_______________________ ❑ %Oxygen:____________________ ❑ Temperature:_________________	❑ 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 ❑ Low oxygen <90% oxygen via pulse oximetry
CLIA-waived POCT Result	❑ Positive for influenza – continue ❑ 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 **REFER TO PCP**
2. If patient is pregnant **REFER TO PCP**
3. If patient has had symptoms >48 hours **REFER TO PCP**
4. If patient is immunocompromised **REFER TO PCP**
   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 **REFER TO PCP**
6. If patient has used antiviral agents for influenza in the past 30 days **REFER TO PCP**

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		
❑ Influenza ADULT ❑ Influenza Prophylaxis Adult	❑ Influenza CHILDREN and ADOLESCENTS ❑ Influenza Prophylaxis CHILDREN and ADOLESCENTS	❑ Refer to PCP

*the following can act as the prescription

ADULT Therapy Options		
Influenza Adult **Treatment**		
❑ Oseltamivir	Dispense: ❑ 75mg #10 No refills	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
❑ Zanamivir	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Baloxavir	Dispense: ❑ 40mg x 1 ❑ 80mg x 1 No refills	Take 1 tablet by mouth now
Influenza Adult **Prophylaxis**		
❑ Oseltamivir	Dispense: ❑ 75mg #7 ❑ 75mg #14 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
❑ Zanamivir	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth once daily x 7 days
❑ Baloxavir	Dispense: ❑ 40mg x 1 (if ≥40kg to 79kg) ❑ 80mg x 1 (if ≥ 80kg) No refills	Take 1 tablet by mouth now

Patient:____.

Prescribed by:____.

Signature:____Date:__________________.

Follow-Up in 48 hours	
Assessment:	❑ If symptoms persist, refer to PCP

Appendix A from Arkansas Statewide Protocol for Treating Influenza

***the following can act as the prescription**

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

Patient:____.

Prescribed by:____.

Signature:____Date:____________________.

Follow-Up in 48 hours	
Assessment:	❑ If symptoms persist, refer to PCP

[Pharmacy Logo] 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):		

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

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

-- FOR PHARMACY STAFF ONLY--

Physical Assessment	**REFER TO PCP** if determined clinically unstable or any of the following criteria
❑ Blood pressure:___________________ ❑ RR:_______________________ ❑ %Oxygen:____________________ ❑ Temperature:_________________	❑ 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 ❑ Low oxygen <90% oxygen via pulse oximetry

Centor Score Assessment		**Interpretation**
Age	❑ 3-14 years: +1 ❑ 15-44: 0 ❑ ≥ 45 year: -1	Total Points: ________________
Exudate or swelling on tonsils	❑ No: 0 ❑ Yes: +1	❑ If Score ≥ 2, proceed in using protocol ❑ If Score < 2, excluded from protocol
Tender/swollen anterior cervical lymph nodes	❑ No: 0 ❑ Yes: +1	
Temperature > 100.4°F	❑ No: 0 ❑ Yes: +1	
Cough	❑ Present: 0 ❑ Absent: +1	
CLIA-waived POCT Result		❑ Positive for GAS – continue ❑ 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 **REFER TO PCP**
2. If patient has taken antibiotics for sore throat or URI in the last 30 days **REFER TO PCP**
3. If patient is pregnant **REFER TO PCP**
4. If patient is immunocompromised **REFER TO PCP**
    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 **REFER TO PCP**

Treat using protocol if:

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

Diagnosis of Patient:		
❑ Strep ADULT ≥18 year	❑ Strep CHILD/ADOLESCENT	❑ Refer to PCP

*the following can act as the prescription

<table>
<tr><th colspan="3">Treatment Options</th></tr>
<tr><td colspan="3">Streptococcal pharyngitis ADULT >18</td></tr>
<tr><td colspan="3">Strep first line treatment options:</td></tr>
<tr><td>❑ Amoxicillin</td><td>Dispense:
❑ 500mg #20
❑ 1000mg #10
No refills</td><td>Sig: 500mg by mouth twice daily for 10 days OR
Sig: 1000mg by mouth daily for 10 days</td></tr>
<tr><td>❑ Penicillin VK</td><td>Dispense:
❑ 500mg #20
No refills</td><td>Sig: 500mg by mouth twice daily for 10 days</td></tr>
<tr><td colspan="3">2nd Line Treatment or Penicillin allergy alternative</td></tr>
<tr><td>❑ Cephalexin</td><td>Dispense ❑ 500mg #20
No refills</td><td>Sig: 500mg by mouth BID for 10 days</td></tr>
<tr><td colspan="3">3rd Line Treatment for Penicillin allergy or equivalent</td></tr>
<tr><td>❑ Azithromycin</td><td>Dispense ❑ 250mg #6
No refills</td><td>Sig: (500mg) by mouth on day 1, then (250 mg) po days 2-5</td></tr>
<tr><td colspan="3">Symptomatic treatments (over the counter)</td></tr>
<tr><td colspan="3">❑ Acetaminophen regular strength (325mg) → 650 mg q4-6hr prn (MAX 3250 mg/day)
❑ Ibuprofen → 200mg q4-6h prn (400mg if no response to 200mg) (MAX 1200mg/day x10 days for pain or x 3 days for fever)
❑ Lozenges/drops containing menthol, dyclonine, benzocaine, or hexylresorcinol
❑ Throat spray containing phenol or benzocaine
❑ 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
❑ Tea/honey → coats throat to provide relief of pain and irritation.</td></tr>
</table>

Patient:____ DOB:______________________

Prescribed by:____

Signature:____Date:______________________

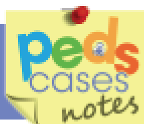
***the following can act as the prescription**

Treatment Options		
Streptococcal pharyngitis CHILDREN AND ADOLESCENTS age 3-17 **Patient weight in kg:________________________________**		
First line treatment option		
❑ Amoxicillin	Dispense: ❑ _____mg (50mg/kg) #10 doses No refills	***MAX daily dose 1,000mg/day*** Sig: 50mg/kg by mouth Daily x10 days
❑ Penicillin VK	Dispense ❑ 250mg #20 doses No refills	Sig: 250mg by mouth twice daily for 10 days
2nd Line Treatment or Penicillin allergy alternative		
❑ Cephalexin	Dispense ❑ _____mg (20mg/kg) #20 doses No refills	***MAX 500mg per dose*** Sig: 20mg/kg/dose by mouth twice daily for 10 days
3rd Line Treatment		
❑ Azithromycin	Dispense ❑ _____mg (12mg/kg) #5 doses No refills	***MAX 500mg per dose*** Sig: 12mg/kg/dose by mouth daily for 5 days
Symptomatic treatments (over the counter)		
❑ 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 ❑ 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) ❑ Lozenges/drops containing menthol, dyclonine, benzocaine, or hexylresorcinol ❑ Throat spray containing phenol or benzocaine ❑ 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 ❑ Tea/honey → coats throat to provide relief of pain and irritation		

Patient:____ DOB:_____________________

Prescribed by:____

Signature:_______________________________________Date:________________________



Pediatric Vital Signs Reference Chart

Heart Rate (beats/min)

Age	Awake	Asleep
Neonate (<28 d)	100-205	90-160
Infant (1-12 mos)	100-190	
Toddler (1-2 y)	98-140	80-120
Preschool (3-5 y)	80-120	65-100
School-age (6-11 y)	75-118	58-90
Adolescent (12-15 y)	60-100	50-90

Respiratory Rate (breaths/min)

Age	Normal
Infant (<1 y)	30-53
Toddler (1-2 y)	22-37
Preschool (3-5 y)	20-28
School-age (6-11 y)	18-25
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:
http://pediatrics.aappublications.org/content/early/2017/08/21/peds.2017-1904

Temperature (°C)

Method	Normal
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.
Screening: axillary, temporal, tympanic (↓ accuracy)
Definitive: rectal & oral (↑ reflection of core temp.)
Reference: CPS Position Statement on Temperature Measurement in Pediatrics (2015)

Oxygen Saturation (SpO_2)

SpO_2 is lower in the immediate newborn period. Beyond this period, a SpO_2 of **<90-92%** may suggest a **respiratory condition** or **cyanotic heart disease**.

Dr. Chris Novak & Dr. Peter Gill for www.pedscases.com
(Edited March 2020 by Richard He)