124966.1123 Reflex Testing policy

Copy of version 2.1 (approved and current)

Last Approval or Periodic Review Completed	2/20/2025
Next Periodic Review Needed On or Before	2/20/2026
Effective Date	7/8/2025

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Organization	UnityPoint Health - St. Lukes

Comments for version 2.0 (last major revision)
Addition of adding on anaerobic cultures for sterilely collected body fluids or tissue.

Comments for version 2.1 (this revision)

added the last revision date

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	2/20/2025	2.0	James Quesenberry MD, FCAP	
Approval	Lab Director	9/24/2024	1.0	James Quesenberry MD, FCAP	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
2.1	Approved and Current	Minor revision	7/8/2025	7/8/2025	Indefinite
2.0	Retired	Major revision	2/10/2025	2/20/2025	7/8/2025
1.0	Retired	Initial version	9/21/2024	9/24/2024	2/20/2025

UnityPoint Health-St. Luke's
Sioux City, Iowa

Title: Reflex Testing, Clinical Interpretations, and Panels

Revisions: 2/2025

Purpose: To define those procedures which always need confirmatory, additional testing or a written interpretation from a Pathologist. The intent of this additional work is to verify and enhance the information of the original test result without the delay to patient care.

Statement: The intent of Reflex Testing, Clinical Interpretations, and Panels are to verify and enhance the information of the original test result without the delay to patient care.

Process for Approval, Change, and/or Remove of a Reflex Test:
Providers should request the addition, change, and/or removal of a reflex test to the Laboratory Director using an SBAR.

- The Medical Director will research best practice for the validity of the request.
- The Medical Director or Executive Director of the Laboratory will then present the request to the Medical Executive Committee (MEC).
- The UnityPoint Health – Sioux City Medical Executive Committee (MEC) will review and approve reflex testing recommended by the Clinical Laboratory.

Policy:

Reflex Testing

Reflex testing is defined as a follow-up test or procedure performed due to the results obtained on the original test request. The following list of tests represents the reflex testing done in the clinical laboratory.

1. Confirmations of urine drugs of abuse (where possible) when screen is positive.
2. Confirmation of Hepatitis B Surface Antigen when screen is positive.
3. Confirmation of HIV4th Generation by HIV 1/2 differentiation test when screen is positive.
4. Confirmations of positive Syphilis IgG Screen with RPR.
5. Sensitivities of significant potential pathogens identified by current microbiology techniques.
6. Gram Stains on cultures determined by clinical site.
7. Susceptibility testing when a BioFire FilmArray Infectious Diarrhea Panel is positive for Shigella or Campylobacter species.
8. Identification of abnormal antibodies found in blood bank screenings, including phenotyping, crossmatch of antigen negative units of red blood cells, titration of antibodies, direct antiglobulin tests, elution, and adsorptions. Consultation with reference lab or blood supplier for difficult

cases such as rare blood types, bone marrow or stem cell transplant patients, and patients with antibodies unidentifiable using our current methods.

9. Smear to Pathologist as defined by criteria or significant cells found in the differential.
10. In an emergency, blood products will be issued according to the emergency release process and may include implementation of the massive transfusion protocol.
11. Collagen/ADP testing for PFA 100 platelet aggregation testing when Collagen/Epinephrine closure time is > 175 seconds.
12. HCV Viral Load by PCR when Hepatitis C Antibody is positive.
13. Clostridium difficile toxin by EIA on positive Clostridium Difficile by BioFire FilmArray Infectious Diarrhea Panel.
14. Every BioFire FilmArray Meningitis/Encephalitis CSF by PCR will include a CSF Culture.
15. Measured LDL is performed when Triglyceride result is >400 mg/dL as calculated LDL is not accurate when Triglyceride is >400 mg/dL or when calculated LDL is a negative number.
16. Positive Fetal Maternal Bleed Qualitative reflex to Quantitative Flow Cytometry Hemoglobin F
17. Positive AFB Smear or AFB Culture reflex to TB PCR +Rifampin resistance test
18. Confirmation of discordant Syphilis IgG Screen with RPR and TPPA
19. Biofire Blood Culture ID, Gastrointestinal, Pneumonia and Respiratory Panels where manufacturer recommends, due to testing limitations identified such as a recall notification, the confirmation of specific testing results (i.e potential false positive, false negative) with alternate method; the laboratory will automatically reflex testing, if testing is available. If alternate testing is not available, comment will be added indicating the need for correlation of test results with clinical symptoms.
20. Serum and urine protein electrophoresis reflex to serum and urine immunofixation if there is a monoclonal peak or the suspicion of a monoclonal peak.
21. GBS Positive patients with a penicillin or cephalosporin allergy will reflex to culture.
22. For any sterilely collected body fluid or tissue on an inpatient (excluding CSF), an anaerobic culture (CANA) will be added on if not previously ordered.

Interpretations by Pathologist

Written interpretations from a pathologist will be included with the following clinical tests and CPT codes.

1. 84165: Protein Electrophoresis, Fractionation/Quantitation, serum.
2. 84166: Protein Electrophoresis, Fractionation/Quantitation, other fluids with concentration (e.g. urine, CSF).

3. 85060: Blood Smear, Peripheral, Interpretation by Physician and Report.
4. 85390: Fibrinolysins or Coagulopathy Screen, Interpretation, and Report.
5. 86334 or 86335: Immunofixation Electrophoresis, serum.
6. 86335: Immunofixation Electrophoresis, other fluids with concentration (e.g. urine, CSF).
7. 85516: Platelet aggregation (in vitro), each agent.
8. 86077: Blood Bank Physician Service, Difficult Cross Match and/or Evaluation of unexpected Antibody, Interpretation and Report.
9. 86078: Investigation of Transfusion Reaction, including Suspicion of Transfusion-transmissible Disease, Interpretation and Report.
10. 86079: Authorization for Deviation from Standard Blood Bank Procedure, with Written Report.
11. 18502: Comprehensive clinical consult with history/medical record review.
12. 89060: Crystal Identification by Light Microscopy with or without Polarizing Lens.
13. 88104: Pathologist's Exam of Wright-stained Cytospin Slide, along with Cell Count of Body Fluid, when no Cytology is Performed.

Ancillary Testing of Tissues such as Surgical, Cytology or Bone Marrows

1. Immunohistochemistry used for purposes of arriving at diagnosis.
2. Molecular testing used for purpose of arriving at diagnosis.
3. Prognostic markers and therapeutic markers such as Her-2 Neu, ER, PR EGFR by immunohistochemistry or molecular methods.
4. Flow cytometry markers for diagnostic purposes.

Panels

As part of the general compliance plan, the laboratory does not routinely offer custom panels without additional Medical Director and Medical Staff approval along with annual review. Panels that are offered by the laboratory are those panels listed in the American Medical Association (AMA) CPT Code book and the approved custom panels below:

- OB panel- ABO & Rh, Ab Screen, HBsAG, Rubella, RPR, CBC w/ diff
- Renal Function Panel- Albumin, Calcium, CO2, Chlorine, Creatinine, Glucose, Phosphorus, Potassium, Sodium, Urea Nitrogen
- Lipitor Panel- Cholesterol, HDL, Triglycerides, CPK, ALT
- Acute Hepatitis Panel- HAVAb-IgM, HBcAB, HBsAg, HCVAb-IgM

Referral Laboratory's Reflex and Interpretation Policies

Tests not performed at UnityPoint Health – St. Luke's laboratory in Sioux City that are referred to reference laboratories may have reflex testing or pathology interpretations as part of their testing protocol. These tests are not listed in this document. Providers should consult the laboratory if questions or problems arise from reflex and interpretation policies at reference laboratories.

Pathologist Interpretations

Pathologists may delegate those circumstances under which a result does not usually require the exercises of medical judgment (interpretation) and may therefore be reported out by a laboratory technician. These circumstances shall be part of the written formal policies and procedures of the clinical laboratory. An attending physician who has demonstrated his desire to forego a Pathologists' clinical diagnostic assistance may do so by a specific notation in the patients' medical record that is communicated to the laboratory.

References: N/A