Sanford Policy Laboratory Fargo Region General:	CRITERIA FOR REJECTION OF SUBOPTIMAL SPECIMENS 2.30
	APPROVED BY: CLINICAL LABORATORY DOCTOR, CONSULTING TECHNOLOGIST, PHYSICIAN - INTERNAL MEDICINE, PHYSICIAN - PATHOLOGY - ANATOMIC & CLINICAL, SENIOR DIRECTOR, LABORATORY OPERATIONS
DATE REVIEWED/REVISED: 09/06/2022	**FORMULATED BY:** DIRECTOR, LABORATORY OPERATIONS

SCOPE: Sanford Amber Valley, Sanford Medical Center Fargo I94 Clinic, Fargo Broadway Clinic, South University, Children's Southwest Clinic, Clinical Care, Osgood Dermatology, Moorhead Clinic, North Fargo Clinic, Southpointe Clinic, Veteran's Square Clinic, West Fargo Clinic, Alexandria Broadway Clinic, Detroit Lakes Clinic, Devils Lake Clinic, East Grand Forks DeMers Ave Clinic, East Grand Forks Demers Derm, East Grand Forks Central Ave Clinic, Edgeley Clinic, Ellendale Clinic, Enderlin Clinic, Finley Clinic, Forman Clinic, Grand Forks Clinic, Grand Forks Patient Service Center, Gwinner Clinic, Halstad Clinic, Hawley Clinic, Hillsboro Medical Center, Hillsboro Clinic, Jamestown 2nd Ave Clinic, Jamestown 5th Ave Clinic, Lamoure Clinic, Lidgerwood Clinic, Lisbon Clinic, Mahnomen Clinic, Mayville Medical Center, Oakes Clinic, Parkers Prairie Clinic, Pelican Rapids Clinic, Thief River Falls Medical Center, Twin Valley Clinic, Ulen Clinic, Valley City Clinic, Wahpeton Clinic, Wheaton Clinic, Wheaton Medical Center, Reproductive Medicine

PRINCIPLE:
Criteria for rejection of suboptimal specimens is defined to ensure that the quality of testing is not compromised by the collection and transport of specimens. Handling and Rejecting Suboptimal Specimens, Laboratory- Enterprise is used as guidance for implementing this procedure.

POLICY:
Specimens that are not labeled, have illegible labels, are mislabeled, or do not contain two patient identifiers will not be accepted for testing. Specimen recollection will be requested. Specimens that cannot be recollected (e.g. irreplaceable specimens) will be tested if determined acceptable by department leadership or the on-call manager. A representative from the collecting department will be required to come to the lab to identify and properly label the specimen before testing. The report on any unlabeled or mislabeled irreplaceable specimen will include the following disclaimer dot phrase: "Interpret results with caution. Specimen not properly labeled/identified" (.identitylabel).

PROCEDURE:
1. Evaluate the specimen to make sure it is acceptable (see criteria below).
2. Call the service area whenever a specimen is rejected so a new specimen can be collected. Order a recollect if warranted.
3. Enter rejection information into the Laboratory LIS and document phone calls to include person receiving the information
4. Label the specimen as "rejected" and place in the rejected specimen area in the laboratory.
5. Do NOT REJECT the following specimens without consulting a lead, supervisor, or manager:
   A. Irreplaceable (tissues, CSF, body fluids) specimens.
   B. Specimens collected by an invasive procedure.
   C. Unique specimens that cannot be replaced.
   D. Specimens collected for microbiology culture. When in doubt plate all specimens collected for culture and refer to the microbiology supervisor.
   E. Enter a "Labeling Follow-Up" task if the specimen was unlabeled or mislabeled.
   F. Consult with leadership to determine if testing will be allowed on the specimen.
      1) The lab must be able to identify the collecting department. Contact the collecting department and have them send someone to the lab to properly identify and label the specimen.
      2) Complete the Unlabeled Mislabeled Specimen Form, Laboratory- Enterprise form and have the person identifying the sample sign it. Scan into Beaker and send a copy with the specimen to other performing lab(s), if necessary. Route a copy to Quality for review.

3) For any unlabeled or mislabeled specimen add a hard hold (can be done by technical staff) to all tests on the specimen with instructions to add an identification disclaimer dot phrase to results.
4) Testing staff will add the disclaimer dot phrase "Interpret results with caution. Specimen not properly labeled/identified" to the report (.identitylabel).

6. If a specimen is mislabeled by the lab (original label correct when received in lab) consult with a supervisor or manager to determine if specimen can be accepted and tested.
7. For specimens that are accepted but the specimen quality is suboptimal:
   A. A specimen hold will be placed by the specimen processor detailing the circumstances, if known or appropriate. For example: "delay in transport".
   B. Suboptimal (compromised) specimen; unable to determine impact to result accuracy (e.g. delay in transport):
      1) The technologist will add a comment to the result using dot phrase ".integrity" which states *"Interpret results with caution. Specimen integrity compromised by (use reason given in order comment)."*
   C. Suboptimal (compromised) specimen; inaccurate result reporting (e.g. compromised with IV fluid, hemolyzed, clotted…):
      1) Test results reported and later determined to be inaccurate:
         a. Tech removes results and replaces with dot phrase ".csremove" which states "*Suspected compromised sample. Result removed at the request *** (enter provider/nurse/lab name)*.
      2) Lab questions validity of results before reporting but provider requests it be reported:
         a. Tech enters result and adds dot phrase ".csreport" which states *"Suspected compromised sample. Reported at the request of *** (enter provider/nurse name).*
8. Quality Assurance
   A. When a specimen is rejected the person(s) involved in the collection will be informed as soon as possible and, if appropriate, educated.
      1) If it is not possible to identify the person involved, or that person is not available, the service area or their supervisor will be notified if known.
      2) For laboratory phlebotomy staff the supervisor or manager will be notified. If the issue is critical or impacts patient care, a supervisor or manager will be contacted immediately.
   B. Notification and corrective action will be documented using one or more of the following mechanisms:
      1) Test Cancellation One Report (BOE reports)
      2) Patient Safety Report
   C. The Test Cancellation One Report will be reviewed at least monthly by a supervisor or manager to look for patterns or trends.
   D. If patterns or trends are identified additional corrective action will be taken. Corrective action can include:
      1) Retraining/remediation
      2) Root cause analysis
      3) Process Improvements
      4) Disciplinary action
   E. Statistics will be compiled by the department manager and presented to staff on a routine basis. The Quality Specialist will make a formal presentation annually.

PROTOCOL FOR RECOLLECTION:

1. The floor will be notified by the technologist when a recollect is needed, whether it is a lab or unit collect.
2. Recollects for the Emergency Room will be called to the assigned nurse.
3. The technologist will document the name of the person the recollect was called to in the comment section when selecting a redraw reason.
4. The technologist will communicate with specimen processing when a phlebotomist is needed to do the recollect.
5. Transfusion specimens that require recollection, are reordered in EPIC by Transfusion or Nursing staff (EPIC Beaker Recollect Steps do not work in transfusion/blood bank computer system).

CRITERIA FOR REJECTION:

1. General guidelines used laboratory wide:
   A. Unlabeled or incorrectly labeled specimens. Specimens without at least two unique identifiers (patient name, MRN or date of birth).
   B. Containers labeled on the lid only will not be accepted.
   C. Leaking containers and grossly contaminated specimens.
   D. Specimens from unauthorized sources (specimens without valid orders).
   E. Specimens without a requisition or computer orders.
   F. Specimens received in a syringe/container with the needle still attached.
      1) Contact the collector and/or their supervisor to educate them that it is lab policy not to accept containers with needles due to safety issues and will not accept them going forward.
      2) Enter a patient safety report.
      3) Events will be monitored and reported at the daily safety brief. A process improvement will be initiated if there is no improvement or an upward trend in events.
   G. Insufficient quantity of specimen.
   H. Specimens that have exceeded stability time.
2. Additional guidelines by specific laboratory area:
   Blood Bank/Transfusion Services
   A. All unlabeled or mislabeled specimens must be recollected.
   B. Grossly hemolyzed specimens require recollection.
3. Chemistry
   A. Visibly hemolyzed specimens that have a Hemolysis Error attached to the result in the Outstanding List require recollection.

Hemolyzed Specimens

Hemolysis can be due to artifact (difficult phlebotomy) or an in-vivo process. Steps are taken to rule out artifact and the provider is notified. Any hemolysis comment should be added directly to the assay affected by the hemolysis level of the sample individually.
1. First hemolyzed specimen: Order a recollect and have a new specimen collected. When possible, have a phlebotomist collect the second specimen if the original was a unit draw, or a have a different phlebotomist collect it if it was a lab draw.
2. If the provider wants the result reported without a redraw, release the result with the dot phrase comment "Hemolyzed. Result reported per Dr. _____". (.hemoreport)
3. Second specimen (recollect) hemolyzed: Call the unit/provider to help determine the course of action. Document all calls in the LIS.
4. Recollect the specimen one more time (for a total of 3 collections, including the original) if the unit/provider requests that it be done. Do NOT collect the specimen more than 3 times.
5. If hemolysis does not resolve report the result with the following dot phrase comment: "Hemolyzed. Hemolysis not corrected after multiple collections" (.hemonotcorrect)
6. Notify the unit/provider that the specimen continues to hemolyze and document the call in the LIS.
7. Once it has been established that recollection will not resolve hemolysis on a certain patient it is no longer necessary to go through the recollect process on subsequent orders during that hospital stay. Add the dot phrase comment "Hemolyzed. Recollect not done. Hemolysis not corrected by multiple collections on previous specimens" (.hemonorecollect)

   B. Specimens collected in a tube with the wrong anticoagulant
   C. Coagulation specimens with clots or an inadequate amount of blood for the tube.
   D. EDTA tubes with clots (A1C, cyclosporine, FK506).
4. Cytology
   A. Evaluate the specimen to make sure it is acceptable.
   B. Criteria for Rejection:

1) Unlabeled or incorrectly labeled specimens. Specimens must have two unique identifiers (patient name, medical record number, date of birth). Do not accept mislabeled or unlabeled specimens unless the specimen is irreplaceable and the individual who collected the specimen can correctly identify the specimen.
2) Specimens from unauthorized sources (without valid orders).
3) Leaking containers with unreadable patient labels.
4) Slides that are broken into small pieces.
5) Specimens without electronic or paper orders.

C. If the ordering provider is able to be identified, they are notified by phone or note in One Chart.
D. Document the rejected specimen.
1) Rejected paps are document using the PAP REJECTION LOG 2.30.L02.
E. Complete a Patient Safety Report for quality risk management.

5. Hematology
A. Specimens with clots or an inadequate amount of blood for the anticoagulant.
B. Specimen collected in a tube with the wrong anticoagulant.

6. Histology
A. Evaluate the specimen to make sure it is acceptable.
B. Criteria for Rejection:
1) Unlabeled or incorrectly labeled specimens. Specimens must have two unique identifiers (patient name, medical record number, date of birth).
2) Container labeled on the lid only will not be accepted.
3) Leaking containers and grossly contaminated specimens.
4) Specimens from unauthorized sources (specimens without valid orders).
5) Specimens from the same source (body site) or specimens that must be differentiated via laterality received in the same container. Each specimen must be in its own container.
6) Specimens without a requisition or computer orders.
7) For specimens that do not meet the 10:1 formalin ratio, more formalin will be placed on the specimen and a safety event is entered.
8) Per CAP requirements, breast specimens cannot exceed 72 hours in formalin. Should a breast exceed the time limit, a safety event will be placed, as well as a note in the case to alert the pathologist that ER, PR, and Her2 neu stains may be compromised.
9) If a specimen container appears empty or contains less than the expected amount, follow process below:
i. Pathologists' assistant or grossing tech who discovers empty container requests a second look from a colleague. Pathologist from the appropriate subspecialty looks at container to verify it is empty.
ii. Notify the unit/provider who collected the specimen.
iii. Notify supervisor or manager
iv. Enter patient safety event
v. Email Risk (RiskManagement-FGO@sanfordhealth.org) and Quality team the patient safety event number and that it relates to a missing irretrievable specimen.
vi. Quality team refers patient safety event to appropriate worklists; include Directors and Risk.

C. Place specimens that meet the above criteria and those not listed into the problem box located in Amber Valley specimen receiving.
1) Contact the collecting department for the specimen and request the individual who collected the specimen to correct the rejection issue.
2) If the specimen comes from an external site, do not send the specimen back to the site. Take photos and send them to the submitting facility to correct the rejection issue.
D. Never discard a rejected specimen without consulting the administrative pathologist.
E. If specimen meets the criteria for rejection, enter a patient safety event. Attach relevant photos.

7. Microbiology
A. Eswabs greater than 48 hours old; Eswabs for *N. gonorrhoeae* or other material greater than 24 hours old.
B. Improper transport or collection container. Examples include:
1) Stool for culture or enteric pathogen panels in formalin.
2) Synovial fluid for culture in EDTA. Gram stains can be performed.

3) Mucous traps sent through the pneumatic tube system.

C. Inappropriate requests. Examples include:
   1) Anaerobic cultures on unacceptable sources: sputum, voided/catheterized urine, feces, vaginal sources.
   2) Foley catheter tip for culture.
   3) 24-hour urine collection for culture.

D. More than one specimen submitted on the same day from the same source (except blood).

E. Inadequate volume of specimen for multiple requests. Microbiology will ask the physician to prioritize requests.

F. Sputum for routine culture contaminated with oropharyngeal microflora.

G. Urine for culture held longer than 2 hours at room temperature. Urine in preservative can be held up to 2 days at room temperature.

H. Stool for culture or ova and parasite exam on patients hospitalized for more than 3 days.

I. Stool for ova and parasite exam with excess barium.

J. Para-Pak Enteric Plus System for stool culture if the pH indicator in the medium has turned yellow (must be red).

8. Molecular
   A. Specimens that have been aliquoted, co-mingled, or accessed for other testing prior to molecular testing will be rejected.
   B. Testing stool specimens for C. difficile DNA will be performed no more frequently than one test per 7 days.

REFERENCES:

1. Manual of Clinical Microbiology. 11th ed. 2015. JH Jorgensen. ASM.
2. Clinical Microbiology Procedures Manual. 4th ed. 2016. AL Leber. ASM.
3. Standards for Blood Banks and Transfusion Services, 29th ed., 2014, AABB.

ATTACHMENTS:

1. SPECIMEN LABELING 4.65
2. PAP REJECTION LOG 2.30.L02
3. Unlabeled Mislabeled Specimen Form, Laboratory- Enterprise
4. Handling and Rejecting Suboptimal Specimens, Laboratory- Enterprise