Sanford Policy Laboratory Fargo Region General:	CRITERIA FOR REJECTION OF SUBOPTIMAL SPECIMENS 2.30
	APPROVED BY: CLINICAL LABORATORY DOCTOR, CONSULTING TECHNOLOGIST, MANAGER, LABORATORY, PHYSICIAN - INTERNAL MEDICINE, PHYSICIAN - PATHOLOGY - ANATOMIC & CLINICAL, Senior Director, Operations
DATE REVIEWED/REVISED: 10/30/2024	**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, Horace Clinic, 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, 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 FOR REJECTION:
1. Specimen determined to be unacceptable for testing (e.g. collected in wrong container type, QNS, clotted, unlabeled) will be canceled and redraw requested (see criteria below and REJECTION OF SUBOPTIMAL SPECIMENS FLOWCHART - 2.30.A02).
2. Call the clinical personnel responsible for patient care (i.e. nurse) or provider whenever a specimen is rejected. Do not report results out, including verbal results, on samples that are unacceptable for testing.
   A. If provider has concerns or requests results to be reported when calling to reject a suboptimal specimen that may affect results contact supervisor, or manager. After hours contact manager on-call.
3. Enter rejection information into the Laboratory LIS and document phone calls to include person receiving the information
4. Place an order for a recollect or use redraw function. Notify collecting staff of need of recollect.
   A. 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).
5. Place a Safe Event for rejected samples. See: SAFE EVENT REPORTING - Fargo Laboratory/Pathology 94.01
6. Label the specimen as "rejected" and place in the rejected specimen area in the laboratory.
7. 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. 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).

8. 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.

CRITERIA FOR REJECTION (Samples that cannot be tested):

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 or transported at incorrect temperature.
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. Refer HEMOLYSIS, ICTERUS, LIPEMIA AND OTHER INTERFERING SUBSTANCES - 24.20.
   B. Specimens collected in a tube with the wrong anticoagulant
   C. EDTA tubes with clots (A1C, cyclosporine, FK506).
4. Coagulation
   A. Coagulation specimens with clots or an inadequate amount of blood for the tube. See COLLECTION, TRANSPORT AND PROCESSING OF BLOOD FOR COAGULATION TESTING 27.20.
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. See SPECIMEN COLLECTION, PROCESSING AND STORAGE FOR ROUTINE HEMATOLOGY TESTING 32.97 and/or PLATELET CLUMPING-PSEUDOTHROMBOCYTOPENIA 32.60.
6. 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.
2) Mislabeled/unlabeled PAPs are considered retrievable and need to be recollected.
E. Complete a Patient Safety Report.

7. 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. The pathologist on call looks at container to verify it is empty.
ii. A photograph of the container and lid are taken.
iii. Notify supervisor or manager.
iv. Notify the unit/provider who collected the specimen.
v. Enter patient safety event.
a. Attach the photo to the event.
vi. Contact Lab Quality team with the patient safety event number and that it relates to a missing irretrievable specimen.
vii. Lab Quality team refers the SAFE event to appropriate worklists; include Directors and Patient Safety.

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.

8. Microbiology
A. If there has been a delay in transport of specimens refer to DISCLAIMER - CANCELLATION GUIDE FOR DELAYED TRANSPORT - 38.25.T03
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. Refer to ANAEROBIC CULTURE GUIDELINES 39.015 for additional information.
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. Stool for culture or ova and parasite exam on patients hospitalized for more than 3 days.
H. Stool for ova and parasite exam with excess barium.
I. Para-Pak Enteric Plus System for stool culture if the pH indicator in the medium has turned yellow (must be red).

9. 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.

PROCEDURE FOR SUBOPTIMAL SPECIMENS:

1. Specimens that produce questionable results or are suboptimal:
A. A specimen hold can be placed by the technical staff detailing the circumstances to prevent autoverification.
2. Questionable results
A. Investigate delta checks, abnormal values, and critical values to determine validity.
1) Check other lab specimens collected at the same time.
2) Did patient receive blood products, have surgery, have dialysis treatment, receive fluids/medication.
3) Consider the possibility of IV contamination, incorrect order of draw, analyzer error, or other variables that may affect specimen integrity.
4) If the investigation determines that the results are valid, results may be reported.
B. If unable to determine a clinical cause for delta check/questionable result, consult clinical personnel responsible for patient for clinical picture, fully describe specimen condition and how it may affect results. Recommend a recollection.
1) Do **NOT** give numeric value if questioning results.
2) Results are not to be reported at nurse discretion, provider must choose to accept questionable results.
C. If clinically indicated, perform a recollect, determine if unit or lab collect and communicate on priority of redraw with appropriate staff. Potential critical results are collected as STAT.
1) If it is a STAT lab collect, verbal hand-off of recollect is required.
2) Recommend another clinical personnel member perform recollect.
3) If original collection was a line draw, recommend lab staff perform a venipuncture.

REPORTING OF SUBOPTIMAL SPECIMENS:

1. Suboptimal irretrievable specimen: unable to determine impact to result accuracy (e.g. delay in transport):
A. 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)."*
2. Suboptimal specimen: inaccurate result reporting (e.g. compromised with IV fluid, hemolyzed, clotted…):
A. Test results reported and later specimen determined to be suboptimal:
1) Tech removes results and replaces with dot phrase ".csremove" which states "*Suspected compromised sample. Result removed at the request *** (enter provider/nurse/lab name)*.
See CORRECTING VERIFIED RESULTS 2.20.

B Lab questions validity of results before reporting but provider requests it be reported:
1) Tech enters result and adds dot phrase ".csreport" which states *"Suspected compromised sample. Reported at the request of *** (enter provider).*
2) If the provider has concerns or requests results to be reported when calling to reject a suboptimal specimen that may affect results contact supervisor, or manager. After hours contact manager on-call. Examples: samples received at unacceptable transport temperatures or clotted heme/coag samples.

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
5. REJECTION OF SUBOPTIMAL SPECIMENS FLOWCHART - 2.30.A02