PURPOSE:

To facilitate the timely and satisfactory resolution of discrepancies identified with specimen orders, labeling, or specimen integrity upon receipt at the laboratory.

SCOPE:

Processing Department

RESPONSIBILITY:

The Medical or Section Director is responsible for ensuring that the procedure is in compliance with CAP and CLIA regulations. The Director must review and approve this procedure at appropriate intervals. The Medical Director may delegate some of the responsibilities to other CLIA/CAP qualified personnel.

The Processing Supervisor/Manager will have the overall responsibility for implementing this procedure. The supervisor/manager is responsible for ensuring that the procedure is followed accurately and that competency documentation is appropriate.

All processors performing this procedure are required to have appropriate training and competency approved. They are responsible for reading, understanding and competently performing this procedure without deviation.

PROCEDURE:

1. **Determining when an order should be made an Exception**

   1) No requisition/ No test marked on the requisition

   2) Empty, leaked, or broken specimen container

   3) Insufficient volume for send out testing

   4) Specimen(s) submitted with no test marked for that type of specimen

   5) Inappropriate or no specimen submitted for test(s) requested

   6) Date of collection >or = 3 days old for most specimens

   7) Instructions on requisition stating that if certain results are positive, negative, increased, or decreased, additional testing should be performed

   8) Specimen is not labeled with patient name or ID; Requisition not labeled with patient name; Different name on specimen versus that on requisition; Test requests that are unclear or ambiguous (ex. titer, hepatitis panel, viral load, chem panel, liver enzymes, thyroid, hepatitis A, B, C, EBV titer, etc.)

9) Anything on the requisition, affecting testing, that seems unclear or questionable. Be sure to leave a detailed explanation of what is unclear.

2. **Different types of exceptions**

1) **Clarify:** When it is unsure if a test written and/or checked on a requisition by the client is correct. This is often the case where multiple tests exist, however slight differences make for different tests *Do not order the test or tests needing to be clarified.

2) **Collection Date/Time:** Many specimens are time sensitive from a few hours to a few days, so it is necessary to know when a specimen was collected. If unsure of time or date of collection an exception should be ordered.

3) **Inappropriate specimen:** When a processor receives an inappropriate specimen, i.e. not frozen, not protected from light, etc. the processor will create an exception. All the tests should be ordered on the requisition, but the inappropriate specimen should be labeled with an except sticker and kept in the appropriate temperature exception handling bin. Do not Run and Hold (R/H) any samples except for samples deemed irretrievable (See the Irretrievable Specimen List).

4) **No Specimen Received:** When a processor has a test marked on the requisition without an appropriate specimen received, all the tests should still be ordered including an exception code and the exception handling form should be filled out accordingly and given to the specialist.

5) **No Test Marked:** When we receive extra specimens with no test marked on the requisition **do not order an exception**, unless it is an irretrievable sample (See Irretrievable Specimen List). If it is deemed an irretrievable sample place an exception on the accession and R/H the sample to the appropriate department.

6) **No Name or ID on Specimen:** When a processor receives a requisition and specimen but there is no name or ID on the sample an exception code must be assigned to that order.

7) **Name Mismatch on Specimen:** Processors should follow the acceptable name/ID procedure; however, if they should get a true name/ID mismatch the tests affected by this name mismatch should not be ordered and order the exception test code . Store the original samples (DO NOT aliquot) at the appropriate temperature in Processing; unless it is deemed an irretrievable sample, then R/H to the appropriate department (See the Irretrievable Specimen List). **The processor must always check the reciprocal to assure if the other patients order was sent that it was processed correctly.**

8) **Empty tube, Leaked Sample or Broken Sample**: If the processor discovers an empty tube, leaked or broken specimen an exception code should be ordered and an exception handling form completed. Label the specimen, if possible, and place in the appropriate temperature exception handling bin.

9) **No Requisition Received:** If a processor receives a specimen with no requisition a blank requisition should be filled out with as much information provided and an exception handling code should be ordered. An exception sticker should be placed on the specimen and kept in the appropriate temperature exception handling bin unless the sample is irretrievable.

10) **Insufficient Volume for Analysis**: If a processor checks specimen requirements of send-out testing and there is not enough sample to perform all testing requested. An exception should be ordered to clarify with the client priority status. Order all testing requested and hold all samples in the appropriate temperature exception handling bin.

3.   To Create an Exception

1) Document what specimen type was received on the requisition. If there is no requisition, complete a blank manual requisition. Fill in as much information as possible, including what was received and processor ID.

2) Order x9060 to add the exception

    a.   In LabLink

        i.   Complete the order with as much information as possible

        ii.   Under "Notes" explain why the specimen is an exception

        iii.   Under "Add Test" type "Except" to pull up order code x9060

        iv.   File the accession

    b.   In Antrim

        i.   Complete the order with as much information as possible

        ii.   On Line 14 explain why the specimen is an exception

        iii.   On Line 15 add order code x9060

        iv.   File the accession

    c.   Label the requisition with the REQ label and place the exception label on the Exception Handling Form and on the specimen

        i.   NOTE: If the specimen is unlabeled, make sure that the unlabeled part is still visible after placing the exception label. If there are multiple specimens, label one and rubberband the rest to it. If there are multiple unlabeled specimens, an exception label will need to be reprinted for each specimen.

3) All problem specimens go straight to the coordinator for resolution. The coordinator will complete the exception paperwork and resolve problems if appropriate.

Coordinator (or designee) Exception Response

1) Review the problem. If it can be resolved in Processing, resolve and send to testing department.

2) If the problem cannot be resolved in Processing, fill out the Exception Sheet, giving as much detail as possible

3) Use the "Exception Handling Run and Hold Chart" to determine where the specimen should go

   a. Take to the department if it is a Run and Hold

   b. Store in the appropriate temperature exception bin in processing if not a Run and Hold

   c. If testing is completely unknown, refrigerate most specimens. DO NOT refrigerate CSF

4) Specimen should be placed in appropriate temperature exception bin located in processing

   a. If test is completely unknown, refrigerate serum-a majority of tests take refrigerated specimen

Run and Hold (R/H)Process

1) In LabLink, under "Notes", note that the specimen was sent for a R/H and to which department. If using Antrim, this goes on line 14.

2) Irretrievable specimens are always sent as R/H

   a. Body Fluids
   b. CSF
   c. Tissue
   d. Bone Marrow
   e. Culture Swabs
   f. Blood Culture Bottles
   g. Microbiology Plates
   h. Bronchial and Tracheal Fluids
   i. Pediatric Microtainers
   j. Drug Screen Chain of Custody (COC)
   k. RPMI

3) R/H all specimens for Molecular Diagnostics and the Microbiology Department except for urine and stool.

4) Extra specimens drawn by BBPL PSC's or phlebotomists should be placed in the processor's clot rack with no additional follow up needed

5) NOTE that weekend processes (Friday night through Sunday night) are slightly different due to the availability of clients for clarification on specimens. **SEE CHART**

WEEKEND Run and Hold (R/H) Chart: Friday 5pm through Sunday midnight			
Specimen	**Problem**	**Procedure**	**Department**
Purple Top	• No test ordered • Any clarification for hematology tests	1. Create an Exception 2. R/H a Heme Profile	3. Take to Core Lab
Blue Top	• Any	1. Create an Exception 2. R/H a ProTime(PT)	3. Take to Core Lab
Urine	• No test marked	1. Create an Exception 2. R/H a Urine C-S 3. R/H a Urinalysis	3. Take to Micro and Core Lab
Urine	• Clarify date/time of collection of urinalysis	1. Create an Exception 2. R/H a Urinalysis	3. Take to Core Lab
Occult Cards	• Clarify date/time of collection	1. Create an Exception	2. Hold in Processing at room temp until resolved
Urine Cup	• Clarify random or 24 hour	1. Create an Exception	2. Hold in Processing refrigerated until resolved
Urology Associates Specimen	• No test marked in the Bladder Tumor Detection Panel Area	1. Create an Exception 2. R/H a BDTP	3. Take to Molecular
Molecular Diagnostics Testing	• No test marked on RPMI sample received • Clarify testing • No name / name mismatch • Clarify date/time of collection	1. Create an Exception	2. Take to Molecular
Microbiology Testing	• No test marked for any microbiology sample • Name mismatch • Clarify date/time of collection	1. Create an Exception	2. Take to Micro
Quantiferon Gold	• Any	1. Create an Exception	2. Incubate in Processing
All Others	• Any	1. Create an Exception	2. Hold in Processing refrigerated until resolved

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WEEKDAY Run and Hold (R/H) Chart			
Specimen	**Problem**	**Procedure**	**Department**
Purple Top	• Clarify date/time of collection	Create an Exception	Hold in Processing refrigerated until resolved
Blue Top	• Clarify date/time of collection	Create an Exception	Hold in Processing refrigerated until resolved
Urine	• No test marked • Clarify date/time of collection	Create an Exception	Hold in Processing refrigerated until resolved
Occult Cards	• Clarify date/time of collection	Create an Exception	Hold in Processing room temp until resolved
Urine Cup	• Clarify random or 24 hour	Create an Exception	Hold in Processing refrigerated until resolved
Urology Associates Specimen	• No test marked in the Bladder Tumor Detection Panel Area	R/H BTDP	Take to Molecular Diagnostics
Molecular Diagnostics Testing	• No test marked on RPMI sample received • Clarify testing • No name / name mismatch • Clarify date/time of collection	R/H all samples except urine and stool samples	Take to Molecular Diagnostics (Hold urine and stool refrigerated in Processing)
Microbiology Testing	• No test marked for any microbiology sample • Name mismatch • Clarify date/time of collection	R/H all Microbiology samples except urine and stool.	Take to Microbiology Department (Hold urine and stool refrigerated in Processing)
Quantiferon Gold	• Any issue	Create an Exception	Incubate in Processing
All Others	• Any	Create an Exception	Hold in Processing refrigerated until resolved

REFERENCES: N/A

RELATED DOCUMENTS: N/A

APPENDICES: N/A