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Approved by:

Medical Director

_____ (Name) _____
(Signature)

_____ (Initials) _____ (Date)

Section Director

_____ (Name) _____
(Signature)

_____ (Initials) _____ (Date)

Laboratory Manager/Supervisor

_____ (Name) _____
(Signature)

_____ (Initials) _____ (Date)

Revision Record

Revision No.	Date	Responsible Person	Description of Change
1			
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Archival Date:	Department Supervisor/Manager :
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Biennial Review

Signature	Title	Date
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Training Record and Signature Log

The following laboratory staff have read and agree to follow the current procedure. In addition, these staff are responsible for signing and/or initialing laboratory records.


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PURPOSE:

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

SCOPE:

All processing personnel generating exceptions on specimens and all client services personnel trained to resolve specimen exceptions.

RESPONSIBILITY:

It is the responsibility of all Processing personnel generating exceptions and all Client Service's personnel resolving exceptions to have read and understand this procedure.

It is the responsibility of every individual processor to recognize and document issues. It will be the responsibility of client services to contact the client and resolve the exception to final disposition.

PROCEDURE INSTRUCTIONS:


For Processing:

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.


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- 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.

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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) Fill out a Exception Sheet with the following:
 - a. Processor #,
 - b. Date/Time
 - c. Specimen Type
 - d. Specimen Temp.
 - e. The reason for the exception
- 4) 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.
- 5) The Requisition and Exception Handling Form should be placed in the Coordinator Review area. The Coordinator will determine if the exception should go to the Client Services Coordinator or if it can be immediately resolved.
- 6) 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

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4. 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 B&B 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	<ul style="list-style-type: none"> No test ordered Any clarification for hematology tests 	<ol style="list-style-type: none"> Create an Exception R/H a Heme Profile 	3. Take to Core Lab
Blue Top	<ul style="list-style-type: none"> Any 	<ol style="list-style-type: none"> Create an Exception R/H a ProTime(PT) 	3. Take to Core Lab
Urine	<ul style="list-style-type: none"> No test marked 	<ol style="list-style-type: none"> Create an Exception R/H a Urine C-S R/H a Urinalysis 	3. Take to Micro and Core Lab
Urine	<ul style="list-style-type: none"> Clarify date/time of collection of urinalysis 	<ol style="list-style-type: none"> Create an Exception R/H a Urinalysis 	3. Take to Core Lab
Occult Cards	<ul style="list-style-type: none"> Clarify date/time of collection 	<ol style="list-style-type: none"> Create an Exception 	2. Hold in Processing at room temp until resolved
Urine Cup	<ul style="list-style-type: none"> Clarify random or 24 hour 	<ol style="list-style-type: none"> Create an Exception 	2. Hold in Processing refrigerated until resolved
Urology Associates Specimen	<ul style="list-style-type: none"> No test marked in the Bladder Tumor Detection Panel Area 	<ol style="list-style-type: none"> Create an Exception R/H a BDTP 	3. Take to Molecular
Molecular Diagnostics Testing	<ul style="list-style-type: none"> No test marked on RPMI sample received Clarify testing No name / name mismatch Clarify date/time of collection 	<ol style="list-style-type: none"> Create an Exception 	2. Take to Molecular
Microbiology Testing	<ul style="list-style-type: none"> No test marked for any microbiology sample Name mismatch Clarify date/time of collection 	<ol style="list-style-type: none"> Create an Exception 	2. Take to Micro
Quantiferon Gold	<ul style="list-style-type: none"> Any 	<ol style="list-style-type: none"> Create an Exception 	2. Incubate in Processing
All Others	<ul style="list-style-type: none"> Any 	<ol style="list-style-type: none"> Create an Exception 	2. Hold in Processing refrigerated until resolved

WEEKDAY Run and Hold (R/H) Chart


Specimen	Problem	Procedure	Department
Purple Top	<ul style="list-style-type: none"> Clarify date/time of collection 	Create an Exception	Hold in Processing refrigerated until resolved
Blue Top	<ul style="list-style-type: none"> Clarify date/time of collection 	Create an Exception	Hold in Processing refrigerated until resolved
Urine	<ul style="list-style-type: none"> No test marked Clarify date/time of collection 	Create an Exception	Hold in Processing refrigerated until resolved
Occult Cards	<ul style="list-style-type: none"> Clarify date/time of collection 	Create an Exception	Hold in Processing room temp until resolved
Urine Cup	<ul style="list-style-type: none"> Clarify random or 24 hour 	Create an Exception	Hold in Processing refrigerated until resolved
Urology Associates Specimen	<ul style="list-style-type: none"> No test marked in the Bladder Tumor Detection Panel Area 	R/H BTDP	Take to Molecular Diagnostics
Molecular Diagnostics Testing	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Any issue 	Create an Exception	Incubate in Processing
All Others	<ul style="list-style-type: none"> Any 	Create an Exception	Hold in Processing refrigerated until resolved

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For Client Services:


1. Calling and Prioritizing Exception Resolutions

- 1) Use the Exception Handling Pending List to verify exceptions
 - a. Run pending list:
 - i. 2 (worklist processing)
 - ii. 4 (pending lists)
 - iii. printer=PTR7
 - iv. worklist=EXCEPT
 - v. include unreceived specimens=Y
 - vi. collection time as of: current date and time defaulted
- 2) Review each problem, to ensure they truly are problems. Resolve any non- problems (e.g. there is a test marked, but overlooked by processing)
- 3) Exceptions should first be sorted by requisitions drawn by BBPL and requisitions drawn by client. Requisitions drawn by BBPL should then be sorted by PSC.
- 4) PSC's should be called first, allowing for ample time if any call backs are needed
- 5) Prioritize all problems not drawn by BBPL in following order
 - a. 1st: Clarify testing
 - b. 2nd: Run/Hold problems
 - c. 3rd: Cancellations and pap smear problems
- 6) Contact client in order of exception priority (see 5 above)
- 7) When calling on an Exception, be sure to understand what question you need to ask the client in order to resolve the problem
 - a. If unsure, contact department impacted by the problem to clarify exactly what you need to ask and what the client's options are
- 8) When contacting client:
 - a. Introduce yourself as an employee of Boyce and Bynum needing to clarify lab orders
 - b. Once the correct person is on the phone, explain the issue with the orders
 - c. If client seems unsure, be sure to find out what he/she is unsure about
 - d. Offer to find out more information for the client and call back if necessary. Never give out any misleading information.
 - e. Never make a decision for the client, offer choices, but do not answer
 - i. Ex. "Clarify Hepatitis panel"
 1. Explain different panels offered
 2. Let the client decide which panel to order
- 9) Once the problem is resolved
 - a. Write the client contact name and resolution on hold sheet
 - b. Date and initial that problem is resolved
- 10) For those Exceptions in which the client will call back, place an inquiry note in Antrim listing contact with brief explanation
- 11) All Exceptions not resolved from the previous day should be a priority for the next day

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2. To Close Out an Exception

- 1) Inquiry notes must be put in Antrim listing who the client contact was with a clear and concise resolution to the problem
 - a. 5 (inquiry)
 - b. 2 (patient inquiry options)
 - c. 1 (patient inquiry)
 - d. "E" for entering inquiry notes
- 2) Order entry verify requisition
 - a. Complete missing information
 - b. Correct incorrect information
 - c. Add/change tests as needed. DO NOT delete x9060
- 3) Release hold
 - a. 3 (results processing)
 - b. 1 (accession entry)
 - c. worklist=HOLD
 - d. enter accession number
 - e. Y to release
- 4) Release the exception or cancel any testing necessary, except for Microbiology testing (3, 1):
 - a. Type 3 (RESULTS PROCESSING) and enter
 - b. Type 1 (ACCESSION ENTRY) and enter
 - c. Worklist: Type EXCEPT and enter, or the worklist of the testing needed to be cancelled
 - d. Accession: Type in the accession number and enter
 - e. Use the cancel code message to cancel any necessary testing and DNR the except result.
 - f. Release? <N>: Press Y for yes and enter. If canceling a test enter "cancel" at the prompt then press Y to release
- 5) Login onto Boyce and Bynum's website and place a QA in the system.
- 6) Remaxi all requisitions to assure all information is entered correctly.
- 7) An (X) must be marked through the original exception barcodes.
- 8) Place new barcodes on the requisition and the Exception Handling Sheet.
- 9) Label any specimens in the Processing exceptions bins that now have orders. Have proper processing/chem employee take custody of exception. If all testing is cancelled, discard the specimen as appropriate.
- 10) All run and hold problems
 - a. Correct department will read inquiry notes and put in results as needed
- 11) Scan all exception requisitions and Exception Handling Forms and file in a separate "Exceptions" folder
- 12) . At the end of the shift, you must print out an exception pending list assuring that there are none outstanding.
 - a. Type 2 (WORKLIST PROCESSING)
 - b. Type 4 (PENDING LIST)
 - c. OUTPUT DEVICE prompt, type printer number you wish to print to
 - d. Number of Copies, enter the number of copies requested
 - e. DELAY prompt, enter through this field
 - f. WORKLIST, enter EXCEPT
 - g. STATS ONLY, enter "N"
 - h. INCLUDE UNRECEIVED SPECIMENS, enter "N"
- 13) Clean out the frozen, room temperature and refrigerated exception tubs.

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14) Miscellaneous

- a. Any test that is ordered and cannot be performed or is not wanted by the client must still be ordered (with concise inquiry notes in Antrim) and then cancelled by the appropriate department which performs the test(s)-if it is a send out test then a blue Test Cancellation sheet must be completed and given to the processing supervisor to cancel the test(s)
- b. All Stat problems need to be called to chemistry as soon as completed!!**
- c. If any tests were run in error, be sure to do billing adjustment and document notation in inquiry notes.

Commonly Encountered Exceptions and Guidelines to Resolve Them

- 1) Clarify Titer: Does the client want IgM, IgG, or both IgG and IgM
 - a. Example EBV titer can be ordered as EBV IgG, IgM, or Comprehensive Panel.
- 2) Clarify Viral Load
 - a. Determine the Infectious Agent-HIV, Hepatitis B or C
 - b. Then determine the test methodology-PCR or bDNA
- 3) Hepatitis Overview:
 - a. There is no Hepatitis IgG testing
 - b. Hepatitis A, B, C-client may be looking for a panel
 - c. Hepatitis Panel-there are a number of Hepatitis panels-explain what panels are offered and what the components of each are
- 4) Culture requests for HSV, Chlamydia, Varicella Zoster, etc., but only serum submitted-generally in these cases the client is looking for antibody testing (Igg or IgM)
- 5) Culturette swabs submitted with no test marked-To determine the test wanted the source of the specimen must be clarified: throat, genital, leg (wound), etc.
- 6) Chlamydia or Viral cultures cannot be performed on culturette swabs
- 7) Viral Transport Media (VTM) submitted: Generally can perform CT/NG by PCR, HSV culture, RSV culture, Chlamydia culture, or Viral Isolation Culture.
- 8) Viral Transport Media (VTM) is not appropriate for routine bacti/micro cultures.
- 9) For Liquid Based Media (LBM) Paps any of the following tests can be ordered
 - a. Liquid Based Pap only
 - b. LBM Pap with reflex to HPV (high or high/low risk)
 - c. LBM Pap with HPV (high or high/low risk)
 - d. LBM Pap with CT/NG
 - e. LBM Pap with HPV (high or high/low risk)and CT/NG (CT: Chlamydia trachomatis
NG: Neisseria gonorrhoea)
 - f. Client can order any combination of these tests
- 10) If a single slide is submitted with a cytology requisition then it should be determined from client if this is a gyn or non gyn slide. The source should then be determined. If the source is genital then it is ordered as a conventional pap smear. If it is a non genital source then it is resolved as a non gyn test order making sure to list the specimen site the specimen was taken from.

SAFETY PRECAUTION:

Follow guidelines within the Boyce and Bynum Pathology Laboratories safety manual.

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SAMPLE TYPE AND VOLUME:

N/A

QUALITY CONTROL: N/A

INTERPRETATION: N/A

REFERENCE RANGE: N/A

EQUIPMENT:N/A

REAGENTS/MEDIA/SUPPLIES:N/A

METHOD: N/A

REFERENCES: N/A

PERFORMANCE SPECIFICATIONS:N/A

CALCULATIONS: N/A

CRITICAL VALUES: N/A

REPORTING RESULTS: N/A

RELATED DOCUMENTS: N/A

APPENDIXES: N/A