Respiratory Specimens – Collection to Reporting: Specimen Accessioning and Processing
Agenda

• Overview of specimen handling and processing
  – Basics of pre-analytical phase
    • Collection
    • Transport
    • Labeling
    • Receipt
    • Rejection
  – Documentation required – do what you write, write what you do

• Exercise: Create a process map for your laboratory from the time the specimen arrives to the time the specimen is ready for testing
  – Define processes that should be documented (SOPs to be written)
  – Define roles and responsibilities
Three Phases of Testing

• Specimen Accessioning and Processing
  – Pre-analytical phase
  – Specimen collection, transport, receipt, and processing

• Laboratory Testing
  – Analytical phase
  – Testing and examination including RNA extraction, RT-PCR, addition into culture medium, HA or HAI testing
  – Review and interpretation of data

• Test Result Reporting
  – Post-analytical phase
  – Creation and review of final report
  – Sending report
Laboratory Testing: Guiding Principles

• The assurance of quality laboratory results relies on a commitment to assess all aspects of the total testing process.
• A problem or error in any of the three phases can invalidate the results of the entire testing process.
• For a Quality Assurance program to be effective, the necessary policies and procedures must be developed and available to staff members.
• Mistakes are best handled by first preventing them and second by addressing them immediately.
  – Do what you write, write what you do.
• Behind every result reported is a patient.
Successful diagnosis depends largely on the quality of the specimen and the conditions for transport and storage of the specimen before it is processed in the laboratory.
Types of Specimens for Influenza Testing

- Respiratory specimens:
  - Nasopharyngeal (NPS) and nasal swabs (NS)
  - Nasopharyngeal (NPA, NPW) and nasal washes or aspirates (NW, NA)
  - Throat swabs (TS)
  - NPS/TS or NP/TS
  - Sputum
  - Endotracheal aspirates (TA, EA, ETA)
  - Bronchioalveolar lavage (BAL)
  - Lung tissue
Specimen Collection

- Tests are most sensitive for influenza when the specimen is collected by 72 hours post symptom onset.
- Person collecting specimen should be trained accordingly.
- References:
  - YouTube channel for Strategies for Improving Rapid Influenza Testing in Ambulatory Settings featuring instructional videos: [http://www.youtube.com/playlist?list=PLNQfL_CJ36fK08KEPjxu1ZKJn7GuFtn-N&feature=plcp](http://www.youtube.com/playlist?list=PLNQfL_CJ36fK08KEPjxu1ZKJn7GuFtn-N&feature=plcp)
Specimen Transport

- Clinical specimens for viral isolation should be placed at 4°C and transported to the laboratory promptly. Specimens for RT-PCR testing only can be frozen.
- Store specimens refrigerated (2-8 °C) before processing. Store any residual specimens at \( \leq -70 \) °C.
- Avoid repeated freeze/thaw cycles.
- If specimen is to be tested by RT-PCR, an aliquot can be inactivated and stabilized in lysis buffer and stored at 4 °C.
Specimen Labeling and Shipping

• Define specimen information as required for forms
  – All sender contact information – keep updated list of contacts
  – Collection date
  – Onset date
  – Patient age and sex
  – Specimen type
  – Unique identifiers
  – Other pertinent information

• Train your submitters
  – Provide correct forms and clearly explain how to complete them
  – Provide an example of how to label tubes properly
  – Provide a demonstration on how to properly package specimens
For any handwritten forms and data worksheets...

- All required information should be complete and accurate
- Writing must be legible
- Abbreviations should be defined on the form or a nearby reference document
- Proper signatures should be obtained in a timely manner
- Contact the submitter as soon as possible if there are any questions or ambiguities
Example Specimen Transfer Form

<table>
<thead>
<tr>
<th>SPECIMEN TRANSFER FORM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Information</strong></td>
</tr>
<tr>
<td>Patient Name: ________________ Gender: &quot; Male &quot; Female Age:</td>
</tr>
<tr>
<td>Address: __________________________________________________ DOB:</td>
</tr>
</tbody>
</table>

| **Referral Site Information** |
| Sending Laboratory Name: ______________________________ Client Code Number: |

| **Specimen Information** |
| Specimen ID Number: ______________ Source/Site: ____________________ |
| Collection Date: ______________ Collection Time: ______________ am / pm Transport Date: |
| Test(s) Requested: ____________________________________________ |
| Additional Information: ________________________________________ |

| **Receiving Laboratory Verification** |
| Receipt Date: ______________ Receipt Time: ______________ am / pm |
| Specimen: " Accepted " " Rejected " Reason for Rejection: ______________ |
| Receiving Officer: ____________________________________________ |
| Signature: ___________________________________________________ |
What is wrong with this form?

SPECIMEN TRANSFER FORM

Patient Information
Patient Name: Smith, Bill                     Gender: ☑ Male ☐ Female Age: 20
Address: 7890 Hill Road Atlanta GA USA          DOB: 04/05/1981

Referral Site Information
Sending Laboratory Name: State Pathogenesis          Client Code Number:

Specimen Information
Specimen ID Number: ABC112                        Source/Site: Hospital X
Collection Date: 02/12/2011 Collection Time: 9:00 am/pm Transport Date:
Test(s) Requested: Influenza Testing
Additional Information:

Receiving Laboratory Verification
Receipt Date: 02/13/2011 Receipt Time: 4:00 am/pm
Specimen ☐ Accepted ☑ Rejected Reason for Rejection: 
Receiving Officer: Jane Doe
Signature: 

Specimen Rejection

• Document the reasons why specimen was rejected
  – Specimen collected in the wrong tube, container, or media
  – Specimen inappropriately handled with respect to temperature, timing, or storage requirements.
  – Quantity not sufficient – QNS
  – Specimen is unlabeled, mislabeled, or improperly or incompletely labeled
  – Specimens in cracked or leaking containers
  – Specimens with inadequate requisition/order slip
• Contact the sender to explain the situation – ask for new specimen, updated paperwork, etc.
• Clean up any hazardous spills, packages according to your biosafety procedures
Documentation of Specimen Receipt

• Establish a laboratory procedure for specimen receipt and train appropriate personnel.

• Document all information on specimen submission form in a log or database.
  – Manual
  – Electronic
  – Review for accuracy as your procedures dictate
  – Supervisory signatures required
## Example Specimen Log

<table>
<thead>
<tr>
<th>Specimen Number</th>
<th>Patient Name</th>
<th>Specimen Type</th>
<th>Sender Name and Contact</th>
<th>Transported by</th>
<th>Specimen Condition</th>
<th>Date Received</th>
<th>Date Tested</th>
<th>Date Reported</th>
<th>Result</th>
<th>Notes</th>
</tr>
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</table>
## What is wrong with this log?

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<th>Result</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>123450</td>
<td>R.K.</td>
<td>Unknown</td>
<td>State PH Lab</td>
<td>AK</td>
<td>cold</td>
<td>02/11/2011</td>
<td>02/12/2011</td>
<td>02/13/2011</td>
<td>InfA-H1</td>
<td></td>
</tr>
<tr>
<td>123451</td>
<td>BL</td>
<td>NPSwab</td>
<td>Hospital X</td>
<td></td>
<td>cold</td>
<td>02/11/2011</td>
<td>02/12/2011</td>
<td>02/13/2011</td>
<td>InfB</td>
<td></td>
</tr>
<tr>
<td>123452</td>
<td>AS</td>
<td>NPwash Lab</td>
<td></td>
<td>RD</td>
<td>broken</td>
<td>02/11/2011</td>
<td>02/12/2011</td>
<td>02/13/2011</td>
<td>SNT</td>
<td>broken tube - not tested</td>
</tr>
<tr>
<td>123453</td>
<td>S.J.</td>
<td>nose</td>
<td>Hospital</td>
<td>AM</td>
<td>cold</td>
<td>02/12/2011</td>
<td>02/12/2011</td>
<td>02/13/2011</td>
<td>Neg</td>
<td></td>
</tr>
<tr>
<td>123459</td>
<td>EG</td>
<td>throatSwab</td>
<td>State PH Lab</td>
<td>AK</td>
<td>Warm</td>
<td>02/12/2011</td>
<td>02/11/2011</td>
<td>02/13/2011</td>
<td>Neg</td>
<td></td>
</tr>
</tbody>
</table>
Completed Pre-Analytical Phase Specimen Receipt Steps

- Patient identification
- Correct specimen labeling
- Proper sample presentation
- Requisition/order matches specimen
- Requisition has accurate contact (ordering party information)
- Specimen in acceptable condition
- Specimen transported appropriately
- Log book entry matches specimen
- Any abbreviations are confirmed
- Date/time of collection is indicated
Specimen Handling

• Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC)

• Use personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents while handling materials including samples, reagents, pipettes, and other equipment and reagents

• Document how specimens are handled, aliquoted, and stored prior to testing
### Specimen Processing Tasks

<table>
<thead>
<tr>
<th>Daily Tasks</th>
<th>Weekly, Monthly, or As-Needed Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Inspect work area</td>
<td>▪ Review referral log; follow-up on any outstanding reports</td>
</tr>
<tr>
<td>▪ Adhere to safety practices; ensure all needed safety equipment is available</td>
<td>▪ Tally workload for all stations</td>
</tr>
<tr>
<td>▪ Organize work area for the day’s workload</td>
<td>▪ Perform weekly and as-needed centrifuge maintenance on all centrifuges</td>
</tr>
<tr>
<td>▪ Ensure all specimens meet the referral test requirements</td>
<td>▪ Issue repair orders and monitor until service is completed</td>
</tr>
<tr>
<td>▪ Aliquot specimens properly as needed</td>
<td>▪ Review supplies and reagents needed at the workstation; update stockroom as needed</td>
</tr>
<tr>
<td>▪ Document and record QA indicators and occurrences</td>
<td>▪ Ensure sufficient workstation logs are available for the next month; provide blank logs at the end of month</td>
</tr>
<tr>
<td>▪ Ensure proper disposal of waste</td>
<td>▪ Observe other members and provide feedback and cross-train as needed</td>
</tr>
<tr>
<td>▪ Clean and disinfect work area</td>
<td>▪ Review and sign-off on all SOPs for the workstation and overall laboratory policies</td>
</tr>
<tr>
<td>▪ Restock work area with all needed supplies for the next day</td>
<td></td>
</tr>
</tbody>
</table>
Procedures (SOPs) for Specimen Processing

• Collection
• Labeling (tube and submission forms)
• Transport
• Receipt and documentation
  – Specimen rejection process
• Processing
• Storage
• Don’t forget training!
Process Maps and Flow Charts

WHY?
• To identify the actual flow or sequence of events in a process that any product or service follows.

WHAT DOES IT DO?
• Shows unexpected complexity, problem areas, redundancy, unnecessary loops, and where simplification and standardization may be possible.
• Compares and contrasts the actual versus the ideal flow of a process to identify improvement opportunities.
• Allows a team to come to agreement on the steps of the process and to examine which activities may impact the process performance.
• Identifies locations where additional data can be collected and investigated.
• Serves as a training aid to understand the complete process.
Process Maps and Flow Charts

HOW DO I DO IT?

1. Determine the frame or boundaries of the process
   - Clearly define where the process starts (input) and ends (final output)
   - Show detail to clearly understand the process and identify problem areas

2. Determine the steps in the process
   - List all major activities, inputs, outputs, and decisions from the beginning of the process to the end

3. Sequence the steps
   - Arrange the steps in the order they are carried out
Specimen Processing: Process Map Exercise

• How are specimens processed in your laboratory?
• List each step from the arrival of the specimen to the point at which the specimen is ready to be tested.
• Write the name of your laboratory’s SOP for each step OR note if an SOP should be written.
• List the name(s) of those responsible for that step.
• Put the steps in order to make a flow chart.
• What is missing?
  – Training your submitters and providing SOPs?
  – Cross-training laboratory staff in case of surge?
Questions?