
ImmuTech Workshop
March 8, 2016
San Ramon, CA

Sheri Goertzen,
MT(ASCP)BB, CLS(CA), CQA(ASQ)
Valley Children’s Hospital
Madera, California
sgoertzen@valleychildrens.org
Objectives

1) Describe methods to effectively use both automation and manual methods to optimize testing and turnaround times.

2) Share ideas on how to keep a large number of generalist CLS competent in the blood bank.

3) Discuss the development of a decision tree for antibody identification when the solid phase antibody screen is positive.

4) Describe some simple ways to meet the CAP method correlation requirements.
A bit about us…

• Not-for-profit, independent children’s hospital serving central California – 356 beds
• Started 60 years ago by 5 young local mothers
Located in the Heart of California, we are the 2\textsuperscript{nd} largest children’s hospital in California and treat more inpatient cases from these 9 counties than any other children’s hospital.
A bit about us…

- Average 6,000 transfusions per year
- AABB and CAP accredited
- CLS Training Program
- Magnet Recognition for Nursing Excellence
A bit about us…

• Pediatric Level II Trauma Center
• ECMO Program
• Resident program affiliation with Stanford Medical School – in progress
Methodologies

- Echo 1 – acquired April 2009
- Echo 2 – acquired June 2012
- Back-up and Alternate Methods:
  - Manual Capture
  - PeG Tube Testing
  - NHance Tube Testing

- Max volume of specimen = 3 mL EDTA
Echo 1 and Echo 2
2 Echos are our Workhorses

- Donor Retypes
- Type & Screens
- AHG Crossmatches
- Antibody ID: Ready-ID, Extend I, Extend II
- Antigen Screening: C,c,E,e,K
- Interfaced – MediTech 5.66
- MediTech Bedside TAR
- Electronic Crossmatching
Competency Assessment

• All 25 CLS working in blood bank are generalists

• How do you keep 25 Core Lab CLS competent to perform all the necessary testing in your blood bank?
  – Full antibody ID studies, including elutions, adsorptions, phenotyping and titers
  – Aliquot, irradiate, pool, volume reduce platelets, mix reconstituted whole blood for exchange transfusions, as well as wash RBC units if needed.
## Competency Schedule – Wet Samples

<table>
<thead>
<tr>
<th>January</th>
<th>July</th>
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</thead>
<tbody>
<tr>
<td>Type &amp; Screen</td>
<td>Antibody Identification</td>
</tr>
<tr>
<td>Crossmatch</td>
<td>Antibody Titer</td>
</tr>
<tr>
<td>DAT</td>
<td></td>
</tr>
<tr>
<td>Antigen Typing</td>
<td></td>
</tr>
</tbody>
</table>

### Annual cGMP Training & Post-Test
- January

### Annual Observation:
- May - June
# Competency Schedule – Written Test

<table>
<thead>
<tr>
<th>April</th>
<th>October</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Radiation Safety</td>
<td>14. Type/Screen: Tube, Capture, Echo</td>
</tr>
<tr>
<td>2. Irradiation of Blood Products</td>
<td>15. Crossmatch</td>
</tr>
<tr>
<td>5. Exchange Transfusion Prep</td>
<td>18. Transfusion Reaction Investigation</td>
</tr>
<tr>
<td>6. Platelet Volume Reduction</td>
<td>19. Antigen Typing (Phenotyping)</td>
</tr>
<tr>
<td>9. Label Check for Modified Products</td>
<td>22. Back-up Patient History Look-up</td>
</tr>
<tr>
<td>11. Request Form Acceptability</td>
<td>24. Age-Related, Critical Values</td>
</tr>
<tr>
<td>12. Use of Cell-Washers</td>
<td>25. Quality Program</td>
</tr>
</tbody>
</table>
Competency Program – Written Test

Points

(5) 1. **Blood Product Return:** A 40 mL aliquot is issued to NICU and returned 14 minutes later because they decided they weren’t ready to start the transfusion yet. What do you do?

(2) Reference:

(5) 2. **Radiation Safety:** Who is allowed to use the Gammasel 3000?

How is access monitored?

What do you do when someone comes to do maintenance on the irradiator?

(2) Reference:

Ask for the reference for each answer.
Competency Program – Written Test

(4) 14. **Retyping Donor Units**: Why do we save segments when retyping units?

(2) Reference:

Misc. Problem-Solving Skills:

(5) 15. **Bloodless Program**: (Real story) It is the weekend and you are working in the blood bank alone. You get a phone call from a gentleman from the bay area, and he says he needs to speak to the person in charge of the Bloodless Program. Where are 2 places you can find the phone number of our Bloodless Program coordinator for this customer?

1. __________________________________________
2. __________________________________________

What is that phone number? __________________________

Comments/suggestions for procedure / method / process improvement:

Ask for suggestions. Use these to improve your procedures/processes.

Provide feedback on each Comment/Suggestion.
## Average TAT Data

<table>
<thead>
<tr>
<th>Ongoing Monitors</th>
<th>Target</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Newborn Workup</strong></td>
<td>&gt; 90% completed, ≤ 90 min</td>
<td>94%</td>
</tr>
<tr>
<td></td>
<td>Average TAT, ≤ 80 min</td>
<td>69 min</td>
</tr>
<tr>
<td></td>
<td>Average STAT TAT, ≤ 60 min</td>
<td>46 min</td>
</tr>
<tr>
<td><strong>Blood Type</strong></td>
<td>&gt; 90% completed, ≤ 90 min</td>
<td>97%</td>
</tr>
<tr>
<td></td>
<td>Average TAT, ≤ 80 min</td>
<td>57 min</td>
</tr>
<tr>
<td></td>
<td>Average STAT TAT, ≤ 60 min</td>
<td>48 min</td>
</tr>
<tr>
<td><strong>Antibody Screen</strong></td>
<td>&gt; 90% completed, ≤ 90 min</td>
<td>96%</td>
</tr>
<tr>
<td></td>
<td>Average TAT, ≤ 80 min</td>
<td>61 min</td>
</tr>
<tr>
<td></td>
<td>Average STAT TAT, ≤ 60 min</td>
<td>48 min</td>
</tr>
</tbody>
</table>
Antibody Identification Process

• Get referral specimens from several small rural hospitals for Antibody ID
  – Gel
  – LISS
• High Risk Maternal/Fetal Center mothers
• Transported Maternal specimens
• Fair amount of Pediatric Antibody patients
  – WAIHA (panagglutinins, rare specificity ID’d)
  – Chronically transfused
Antibody ID Decision Tree

Positive Antibody Screen Solid Phase

Solid Phase Panel/s

NEGATIVE

PeG Screen

POSITIVE

(ABSCAP) Ab Screen Capture: Positive
(ABCAPR) Antibody ID: Report as
“Nonspecific w/Solid Phase”
(Continue investigation with tube)

PeG Panel/s

YES
Identify Antibody

NO

(ABSTUBE) Ab Screen Tube: Negative
AHG Crossmatch

NO

Report Antibody Specificity, provide
Antigen Neg units, AHG Crossmatch

YES
Identify Antibody

(ABSTUBE) Ab Screen Tube: Positive
ABAHG Antibody ID: Report as
“Nonspecific w/Tube Testing”
AHG Crossmatch

Unidentified antibody choices in menu:
(select the most suitable based on your testing)

INC Inconclusive
NON Nonspecific
NONCAP Nonspecific w/Solid Phase
NONTUBE Nonspecific w/Tube Testing
OCC Und. Reacts w/Occasional RBC
UND Undetermined Specificity
UTD Unable to Determine
UTI Unable to Identify
Positive Solid Phase Ab Screen

Positive

Solid Phase Panel(s)

Negative

Identify Ab

Yes

Report Ab Specificity, provide Ag Neg units, AHG XM

No

Ab Screen Capture = Positive Report as “Nonspecific w/Solid Phase” (continue investigation in tube)

PeG Screen
... continued

PeG Screen

Positive

PeG Panel(s)

Identify Ab

Yes

Report Ab Specificity, provide Ag Neg units, AHG XM

No

Ab Screen Tube = Positive
Report as “Nonspecific w/Tube Testing”, AHG XM

Negative

Ab Screen Tube = Negative, AHG XM
Summary

• If we get Positive reactions with Capture,
  then Negative reactions in the Tube,
  we result the Capture screen as “Nonspecific with Solid Phase”
• and result the Tube Screen as “Negative”
  – We choose to require AHG crossmatching
  – Some facilities do not, but with 25 rotators, it helps me sleep better at night…
Method Correlation

• Required by CAP

• CAP Checklist: COM.04250

  If the laboratory uses more than one nonwaived instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for comparability of results.

• Now applies to blood bank as well as the other clinical lab departments
Method Correlation

• NOTE: This requirement applies to tests performed on the same or different instrument makes/models or by different methods. The purpose of the requirement is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. This comparison must include all nonwaived instruments/methods. The laboratory must establish a procedure for this check that includes acceptance criteria.
Method Correlation

- Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number. Otherwise, the use of human samples (whole blood, serum, plasma, urine, etc.) rather than stabilized commercial controls, is preferred to avoid potential matrix effects.
Method Correlation

• Evidence of Compliance:
  ✓ Written procedure for performing instrument/method comparison AND
  ✓ Records of comparability studies reflecting performance at least twice per year with appropriate specimen types
Method Correlation

- **Method Correlation** is performed twice a year, comparing Echo1 vs. Echo2 vs. Manual Capture vs. Tube methods
  - **ABO/Rh** – No less than 3 specimens are compared, each with different blood types, at least one should be Rh negative
  - **Antibody Screen** – No less than 3 specimens are compared, at least one should be positive
  - **Antigen Typing** – comparing tube to Echo, no less than 3 specimens
  - **Antibody ID** – No less than 1 positive specimen is compared
Method Correlation

• **Interpretation/ Acceptance Criteria:**
  • Manual and Automated Capture methods are expected to correlate closely.
  • Echo1 vs. Echo2 results are expected to correlate (match) closely.
  • Capture vs. Tube methods are expected to show some variability between reactions due to the differences in the nature of the testing systems and enhancements.
  • Corrective action must be taken and documented when criteria are not met.
## Method Correlation: ABO/Rh

<table>
<thead>
<tr>
<th>Lot # of Supplies/Reagents</th>
<th>Tube</th>
<th>Manual Capture</th>
<th>Echo 1</th>
<th>Echo 2</th>
<th>Accept? * Yes or No</th>
<th>Date</th>
<th>Tech</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ABO/Rh</strong></td>
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<td>Specimen #</td>
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<tr>
<td>Capture Strip</td>
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<td>Anti-A</td>
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<td>Anti-B</td>
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<tr>
<td>Anti-D1 (ser.4)</td>
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<td>Anti-D2 (ser.5)</td>
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<td>Weak D</td>
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<tr>
<td>Interp.</td>
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<td>N/A</td>
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</tbody>
</table>

* Interpretation results must match closely between manual and automated Capture methods. Some variability is expected and acceptable between Capture and Tube methods due to the different nature of the test methods.

Reviewed __________________________ Date ______________ Instrument/Method Correlation Acceptable?  Y / N

Must be performed at least twice per year (CAP TRM.31450) and corrective action documented when criteria are not met.
**Method Correlation: Ab Screen, Ag Typing, Ab ID**

<table>
<thead>
<tr>
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<th>Echo 1</th>
<th>Echo 2</th>
<th>Accept? * Yes or No</th>
<th>Date</th>
<th>Tech</th>
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<tbody>
<tr>
<td>Ab Screen</td>
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<td>Capture Strip</td>
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<td>SC1 AHG</td>
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<td>SC2 AHG</td>
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<td>SC3 AHG</td>
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<td>Interp.</td>
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<tr>
<td>Antigen Typing</td>
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<td>Specimen #</td>
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<tr>
<td>Antigen/Sera ___</td>
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<td>Interp.</td>
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<td>Ab ID</td>
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<td>Specimen #</td>
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<td>Tube</td>
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<td>Capture</td>
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<tr>
<td>Interp. (attach panels)</td>
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</tbody>
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Thank You!

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