Policy and Procedure
Dignity Health Central Coast Service Area

**SUBJECT**: Method Correlation

**Laboratory Policy Number: 7540.BBF.CC.240**

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| --- |
| **Central Coast Service Area North:** |
| [x]  Santa Maria Campus,Marian Regional Medical Center | [x] Arroyo Grande Campus,Marian Regional Medical Center | [x] French Hospital Medical Center |
| **Central Coast Service Area South:** |
| [ ] St. John’s Pleasant Valley Hospital | [ ] St. John’s Regional Medical Center |

# Purpose:

Provide guidance on the performance of correlation testing for analytes that are reported using more than one methodology.

# Clinical Complexity:

High complexity

# Clinical Utility:

# Method correlations must be performed twice a year to determine if the different methodologies employed in our Transfusion Service are clinically comparable.

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| --- | --- | --- |
| **Assay** | **Gel** | **Tube** |
| Antibody Screen | 🗸 | 🗸 |
| Antibody Identification | 🗸 | 🗸 |
| Alternative Crossmatch | 🗸 | 🗸 |
| Cord Blood Anti-IgG Direct Antiglobulin Test (DAT) | 🗸 | 🗸 |

# Principle:

The laboratory must evaluate the results of analytes that are tested utilizing different methodologies. The correlations must be documented and performed at least once every six months and include defined tolerance limits for acceptance.

# Specimen Collection:

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| --- | --- | --- | --- | --- |
| **Sample Type** | **Container** | **Minimum Volume** | **Specimen****Stability** | **Storage Temperature** |
| Whole Blood | Pink top EDTA | 6 mL | 14 days  | 2-8°C |
| Cord blood  | Lavender EDTA | 3 mL | 3 days  | 2-8°C |

1. Antibody Screen, Antibody Identification:
	1. Semi-annually select six 6 mL pink top EDTA specimens with enough sample volume for performance of gel and tube antibody screen and antibody identification.
	2. Of the six specimens at least three must have a positive antibody screen and require antibody identification.
2. Crossmatch:
	1. Semi-annually select six 6 mL pink top EDTA specimens with enough sample volume for testing by gel and tube methodologies.
	2. For each specimen select one compatible and one incompatible red blood cell and remove a segment from each unit and place into a test tube labeled with the donor identification number (DIN).
3. Cord Blood Anti-IgG DAT:
	1. Semi-annually select six lavender EDTA cord blood specimens with enough sample volume for testing by gel and tube methodologies.
	2. Of the six specimens at least two must have a positive Anti-IgG direct antiglobulin test.

# Materials:

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| **Reagents** | **Supplies / Materials** | **Equipment** |
| * Antibody screen cells (3% and 0.8%)
* Antibody ID panel cells (3% and 0.8%)
* Anti-Human Globulin IgG gel card
* Anti-IgG
* Coombs control cells
 | * Test tubes
* Pipette and pipette tips
* 0.85% Saline
* RBC segments
* Marking pen
 | * Ortho Workstation
* Serofuge
* Cell washer
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# Maintenance:

## Refer to equipment procedures for applicable maintenance schedules and instruction for performance.

# Calibration:

## Refer to equipment procedures for applicable calibration schedules and instruction for performance.

# Quality Control:

## Quality control must be performed each calendar day of reagent use.

### Refer to 7540.BB.CC.201 Reagent Quality Control- Daily for performance of daily quality control of reagents.

# Procedure:

## Antibody Screen and Antibody Identification

### Select six specimens with enough volume for antibody screen and antibody identification to be performed in parallel by gel and tube methodologies. At least three of the six specimens must have a positive antibody screen.

### Perform the following assays:

* Antibody screen by gel method
* Antibody identification by gel method, if indicated
* Antibody screen by tube method
* Antibody identification by manual tube method, if indicated

### Record reactivity and interpretation on the appropriate manual worksheets for antibody screen and antibody identification.

### Record interpretation on the facilities appropriate method correlation form.

## Crossmatch by Indirect Antiglobulin Test

### Select six specimens with enough volume for a crossmatch to be performed in parallel with one compatible and one incompatible red blood cell by gel and tube methodologies.

Note: The tube method will only include readings at the indirect antiglobulin testing (IAT) phase.

### Record reactivity and interpretation on the appropriate manual worksheets for compatibility testing.

### Record interpretation on the facilities appropriate method correlation form.

## Cord Blood Anti-IgG Direct Antiglobulin Test

### Correlation applicable to Marian Regional Medical Center and French Hospital Medical Center only.

### Select six specimens with enough volume for an Anti-IgG direct antiglobulin test (DAT) to be performed by gel and tube methodologies. At least two specimens must be positive.

### Record reactivity and interpretation on the appropriate manual worksheets for DAT.

### Record interpretation on the facilities appropriate method correlation form.

# Interpretation of Results:

## This process assesses agreement between comparable methods with respect to specificity and sensitivity and positive and negative predictive values.

### It is expected that the result interpretations of antibody screening (i.e. Pos or Neg) will not differ between gel and tube methodologies.

### It is expected that the result interpretations of antibody identification for clinically significant antibodies will not differ between gel and tube methodologies.

### It is expected that the result interpretations of IAT compatibility testing (i.e. Comp or Incomp) will not differ between gel and tube methodologies.

### It is expected that the result interpretations of Anti-IgG DAT testing (i.e. Pos or Neg) will not differ between gel and tube methodologies.

## If method correlations do not agree, then notify the transfusion service area specialist or designee immediately.

## The transfusion service area specialist or designee will investigate all method correlations that do not agree and will include documentation of laboratory medical director notification, provider notification when applicable, and corrective action.

## The transfusion service area specialist or designee will review worksheets to ensure that reactivity is comparable between both methodologies. Comparable reactivity is defined as ± 1 grade of reactivity.

## The laboratory medical director will perform the final review and approval of the completed method correlations.

# Limitations of Procedure:

## The gel methodology may not detect certain antibodies such as Anti-K and Anti-E.

## Rouleaux may cause interference in the gel methodology and therefore should not be used for correlation studies.

# References:

## Fung MK, Grossman BJ, Hillyer CD, Westhoff CM. *Technical manua*l. Bethesda, MD: American Association of Blood Banks; Current Edition.

## *Standards for blood banks and transfusion services*. Bethesda, MD: American Association of Blood Banks; Current Edition.

## *Comprehensive accreditation manual: CAMLAB for laboratory and point-of-Care testing*. QSA.02.08.01. Oakbrook Terrace, IL: The Joint Commission; Current Edition.

# Related Documents:

## 7540.BB.CC.114 Antibody Screen by Manual Gel Procedure

## 7540.BB.CC.115 Antibody Screen by Tube Indirect Antiglobulin Test (IAT)

## 7540.BB.CC.151 Selecting and Testing Reagent Red Cells for Antibody Identification

## 7540.BBF.CC.240 Method Correlation Form

## 7540.BBF.CC.240.1 Method Correlation Form

## 7540.BB.CC.145 Tube Indirect Antiglobulin Testing Crossmatch Procedure

## 7540.BB.CC.146 Manual Gel Indirect Antiglobulin Testing Crossmatch Procedure

## 7540.BB.CC.172 Direct Antiglobulin Test by Gel Method

## 7540.BB.CC.116 Direct Antiglobulin Test by Tube Testing

# Appendixes:

## 7540.BBF.CC.240 Method Correlation Form

### Marian Regional Medical Center and French Hospital Medical Center

## 7540.BBF.CC.240.1 Method Correlation Form

### Arroyo Grande Community Hospital

**Antibody Screen Correlation**

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| --- | --- | --- | --- |
| **Accession Number** | **Gel Antibody Screen****Result Interpretation (\*Pos/Neg)** | **Tube Antibody Screen****Result Interpretation (\*Pos/Neg)** | **Correlation Acceptable****(Yes/No^)** |
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\*For samples with a positive antibody screen by gel and/or tube method, antibody identification by the same method must be performed.

^Unacceptable correlation must be further investigated and corrective action notated.

**Antibody Identification Correlation**

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| --- | --- | --- | --- |
| **Accession Number** | **Gel Antibody Identification****Result Interpretation** | **Tube Antibody Identification****Result Interpretation** | **Correlation Acceptable****(Yes/No^)** |
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**Indirect Antiglobulin Test Crossmatch Correlation**

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| --- | --- | --- | --- | --- |
| **Accession Number** | **Donor Identification Number** | **Gel** **Indirect Antiglobulin Test Crossmatch****(Comp/Incomp)** | **Tube** **Indirect Antiglobulin Test****Crossmatch****(Comp/Incomp)** | **Correlation Acceptable****(Yes/No^)** |
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**Cord Blood Anti-IgG Direct Antiglobulin Test Correlation**

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| **Accession Number** | **Gel Anti-IgG Direct Antiglobulin Test****(Pos/Neg)** | **Tube Anti-IgG Direct Antiglobulin Test****(Pos/Neg)** | **Correlation Acceptable****(Yes/No^)** |
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Attach copies of all manual worksheets, and antibody identification panel worksheets. Copies must be dated and initialed by the CLS performing the testing.

Refer to 7540.BB.CC.240 Method Correlation Procedure Interpreting Results section in order to determine acceptability of results between comparable methods.

Results Agree? (Circle one) YES NO

If NO, transfusion service area supervisor or designee notified? (Circle one) YES NO Date/Time of notification:

Corrective action:

Reviewed By: Date:

Laboratory Medical Director Review: Date:

**Antibody Screen Correlation**

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| --- | --- | --- | --- |
| **Accession Number** | **Gel Antibody Screen****Result Interpretation****(\*Pos/Neg)** | **Tube Antibody Screen****Result Interpretation****(\*Pos/Neg)** | **Correlation Acceptable****(Yes/No^)** |
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\*For samples with a positive antibody screen by gel and/or tube method, antibody identification by the same method must be performed.

^Unacceptable correlation must be further investigated and corrective action notated.

**Antibody Identification Correlation**

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| --- | --- | --- | --- |
| **Accession Number** | **Gel Antibody Identification****Result Interpretation** | **Tube Antibody Identification****Result Interpretation** | **Correlation Acceptable****(Yes/No^)** |
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**Indirect Antiglobulin Test Crossmatch Correlation**

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| --- | --- | --- | --- | --- |
| **Accession Number** | **Donor Identification Number** | **Gel****Indirect Antiglobulin Test Crossmatch****(Comp/Incomp)** | **Tube** **Indirect Antiglobulin Test****Crossmatch****(Comp/Incomp)** | **Correlation Acceptable****(Yes/No^)** |
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Refer to 7540.BB.CC.240 Method Correlation Procedure Interpreting Results section in order to determine acceptability of results between comparable methods.

Results Agree? (Circle one) YES NO

If NO, transfusion service area supervisor or designee notified? (Circle one) YES NO Date/Time of notification:

Corrective action:

Reviewed By: Date:

Laboratory Medical Director Review: Date: