**Purpose**

To provide instructions for performance of method comparison between automated solid phase testing and manual tube testing.

**Background**

CAP Checklist COM.04250 Comparability of Instrument/Method Phase II states “if the laboratory uses more than one 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.

**Scope**

The scope of this protocol is limited to comparison of the following tests using both TANGO solid phase testing, and manual tube testing:

* ABO
* Rh
* Antibody Detection
* Antibody Identification
* Unit type confirmation

**Roles and Responsibilities**

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| **Role** | **Responsibility** | **Related Documents** |
| MLS Staff | Will perform testing and submit results for comparison and evaluation. | * Method Correlation Form
 |
| MLS Lead | Will review sample selection to insure all tests are represented. |
| TS Manager | * Will schedule test correlation on a semi-annual basis.
* Will evaluate test results.
* Will initiate corrective action if indicated.
* Will complete summary report.
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**Sample Selection**

* Samples to be used in the method comparison include the following:
* Patient samples
* Donor cells for ABO/Rh confirmation
* CAP samples can be used for comparison once test results from CAP are available.
* Mix of different ABO/Rh types for ABO/Rh comparison
* Mix of positive and negative for antibody detection comparison
* Single or multiple antibody(ies) for antibody identification
* Minimum numbers of samples to be used for comparison:
* 12 Patient samples for ABO/Rh method comparison between TANGO and manual tube methods.
* 12 Patient samples for Antibody Detection method comparison between TANGO and tube LISS IgG methods.
* 6 Patient samples for Antibody Identification method comparison between TANGO and tube LISS IgG methods.
* 12 Donor samples for type confirmation method comparison between TANGO and manual tube methods.
* 6 Patient samples for antibody detection method comparison between PEG and LISS

**Acceptance Criteria**

* Patient samples for ABO/Rh must have 100% correlation for interpretation of test results.
* Donor samples for ABO/Rh confirmation must have 100% correlation for interpretation of test results.
* Patient samples for Antibody Detection must correlate based on differential sensitivities of various antibodies being tested.

**References**

College of American Pathologists Accreditation Program All Common Checklist