**Purpose**

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

**Background**

CAP Checklist TRM.31450 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 correlation 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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| --- | --- |
| CT Staff | Will perform testing and submit results for comparison and evaluation. |
| CT 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. |

**Sample Selection**

* Samples to be used in the method comparison include the following:
* Patient samples
* Donor cells requiring ABO/Rh confirmation prior to being placed in available status in inventory.
* 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.

**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**

CAP Inspection Checklist TRM.31450 , 7.31.20