|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Policy Statement | When more than one instrument/method is used to test for a given analyte the instruments/methods are checked against each other at least twice a year for comparability of results. | | | |
| Purpose | To ensure that results are reproducible between different instruments/methods within acceptable limits. | | | |
| Scope | This applies to all testing in the Transfusion Services. | | | |
| Responsibility | The Medical Director is responsible for review and approval of comparability studies.  The Lead Technologist or designee is responsible for ensuring comparability studies are performed in their required timeframes and for documenting the comparability study report.  The Medical Technologist (I and II) is responsible for performing comparability studies when instructed. | | | |
|  | | | | |
| Study Testing Required | **Tube Testing** | **Manual Gel** | | **ProVue Gel** |
| Blood Type |  | | Blood Type |
| DAT | DAT | |  |
| Antibody Screen | Antibody Screen | | Antibody Screen |
| Antibody ID | Antibody ID | |  |
| Number of Tests for Comparability Study | Blood Type | | 1Rh-positive, 1Rh-negative | |
| DAT | | 1positive, 1negative | |
| Antibody Screen | | 1positive, 1negative | |
| Antibody ID | | Positive Screens from Comparability Study | |
| Study Schedule | Two comparability studies are required each year. The required number of tests for each comparability study should be completed and documented during the first half of the calendar year and again during the second half of the calendar year. | | | |
| Selection of Samples | Select samples for comparability studies based on the results from the primary method of testing; e.g. the primary method of testing blood type is the ProVue analyzer. Select 5-Rh-positive and 5 Rh-negative samples from ProVue testing to compare against tube testing. | | | |
| Documentation of Comparability Study | The results and interpretation of testing will be displayed in tables in a written report, see TRAN 6500 F. Discrepancies between methods will be explained in the written report accompanying the results and interpretations. | | | |
| Criteria for Acceptability | It is well known that the methods used in the identification of antigens and antibodies have differences in sensitivity and specificity; different enhancement media, incubation times and temperatures, cell suspensions and patient-related variables all interplay. Some antigens and antibodies are only able to be identified under specific circumstances. This variation is used to assist the technologist in the identification process, especially when a patient has multiple antibodies, antibody of undetermined specificity and/or warm/cold autoantibodies. This variation should not be presented between instruments of the same model and version.  The lead technologist or designee who reviews the comparability study will determine whether any discrepancy between results or interpretation are acceptable and forwards this to the medical director for approval. | | | |
| References | Rumsey, DH, Ciesielski, DJ. “New protocols in serologic testing: a review of techniques to meet today’s challenges.” Immunohematology. 2000; 16(4): 131-137.  Novaretti, MC, Silveira, EJ, Filho, EC, Dorlhiac-Llacer, PE, Chamome, DA. “Comparison of tube and gel techniques for antibody identification.” Immunohematology. 2000; 16(4): 138-141.  Das, SS, Chaudhary, R, Khetan, D. “A comparison of conventional tube test and gel technique in evaluation of direct antiglobulin test.” Hematology. 2007 Apr; 12(2): 175-178. | | | |