Complying with College of American Pathologists (CAP) TRM.31450 Comparability of Methods: A Simple and Convenient Solution

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INTRODUCTION

Regulations from multiple entities require comparability of test results when laboratories use more than one method of testing for a given analyte. Furthermore, the laboratory must have a system in place to evaluate and define the relationship between these methods twice per year. The actual regulations are quoted nearby as background.

Creating an easy-to-use and suitable protocol that would fulfill the requirements for comparability of methods in Antibody Detection and Antibody Identification has been challenging. The purpose of this study was to determine whether a convenient, commercially available product, the ALBAcheck® Competency Testing Kit from Quotient could satisfy the requirement for a sample source, and thus simplify our comparability of methods protocol.

REGULATIONS

The Code of Federal Regulations has long required a comparison of test results when different methodologies are used to perform the same test.[1]

42 CFR 493.1281 Standard: Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

Transfusion Service laboratories became more aware of the requirement when TRM.31450 was added to the College of American Pathologists (CAP) Transfusion Medicine Checklist. TRM.31450 requires a laboratory using more than one method for a given analyte to compare those methods against each other at least twice a year.[2]

TRM.31450 Comparability of Instrument/Method Phase II

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.

NOTE:This requirement applies to tests performed on the same or different instrument makes/models or by different methods. This comparison must include all nonwaived instruments/methods. The laboratory director must establish a protocol for this check. 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, rather than stabilized commercial controls, is preferred to avoid potential matrix effects. The use of pooled patient samples is acceptable since there is no change in matrix. In cases when availability or pre-analytical stability of patient/client specimens is a limiting factor, alternative protocols based on QC or reference materials may be necessary but the materials used should be validated (when applicable) to have the same response as fresh human samples for the instruments/methods involved.

Evidence of Compliance:
✓ Written procedure for performing instrument/method correlation including criteria for acceptability **AND**
✓ Records of correlation studies reflecting performance at least twice per year with appropriate specimen types

Although the requirement was moved from the Transfusion Medicine Checklist to the All Common Checklist in 2014, the wording is essentially the same.[3]

****NEW** 04/21/2014**
COM.04250 Comparability of Instruments/Methods Phase II

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.

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 is required only for nonwaived instruments/methods accredited under a single CAP number. The laboratory must establish a protocol for this check that includes acceptance criteria.

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, rather than stabilized commercial controls, is preferred to avoid potential matrix effects. The use of pooled patient samples is acceptable since there is no change in matrix. In cases when availability or pre-analytical stability of patient/client specimens is a limiting factor, alternative protocols based on QC or reference materials may be necessary but the materials used should be validated (when applicable) to have the same response as fresh human samples for the instruments/methods involved.

This requirement only applies when the instruments/reagents are producing the same reportable result.

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

DEFINITION of CHALLENGE

The Transfusion Service faces multiple challenges when developing a comparison protocol for antibody detection and identification.

Several variables must be taken into account, not the least of which is the availability of antibody positive plasma samples.

These antibody positive plasma samples must:

- Reliably demonstrate reactivity when tested by different methods employing multiple enhancement media
- Be available in sufficient quantity for testing by multiple methods
- Retain sufficient antibody strength without deterioration until such time as they can be used in the Comparability of Methods testing.

Any one of these factors may derail comparability of results.

Our laboratory developed a simple process for our twice annual Comparability of Methods challenge. Our process incorporates a commercial product, the Quotient ALBAcheck® Competency Testing Kit as the source of antibody plasma samples.

METHODS

Routine test methods employed in our blood bank include: Column Agglutination Technology (CAT), commonly referred to as Gel by Ortho Clinical Diagnostics (OCD) (Raritan, NJ), manual tube PeG, manual tube LISS and manual tube with no enhancement. We performed antibody screens on each sample from the Quotient ALBAcheck® Competency Testing Kit. Each sample was tested by each of our routine test methods. Ortho Clinical Diagnostics (OCD) 3% reagent red blood cells were used for tube methods and OCD 0.8% reagent red blood cells were used for the CAT (Gel) method. Reaction strength was graded 0-4+. IgG coated cells were added to all negative antiglobulin tube tests.

Antibody identification was performed using CAT (Gel) method and OCD 0.8% reagent red blood cell panels for each of the nine samples that demonstrated a positive antibody screen. The antibody specificities we identified were compared to the manufacturer's expected results for each test kit sample.

RESULTS

SCREENING CELL PHENOTYPE	GEL ANTI-IgG	TUBE PEG ANTI-IgG	TUBE LISS ANTI-IgG	TUBE NO ENHANCEMENT ANTI-IgG
Sample 272896 / Anti-E, Anti-Fy[a]				
SC I E- Fy(a+)	2+	3+	3+	2+
SC II E+ Fy(a-)	3+	4+	3+	2+
Sample 201034 / Anti-K				
SC I K+	2+	2+	1+	1+
SC II K-	0	0	0	0
Sample 681298 / Anti-D				
SC I R1R1	3+	2+	2+	2+
SCII R2R2	3+	2+	2+	2+
Sample 276526 / Anti-E				
SC I E-	0	0	0	0
SC II E+	2+	2+	1+	1+
Sample 642605 / Anti-D				
SC I R1R1	3+	3+	2+	2+
SC II R2R2	3+	3+	2+	2+
Sample 358444 / Anti-Fy[a]				
SC I Fy(a+)	2+	2+	2+	1+
SC II Fy(a-)	0	0	0	0
Sample 143740 / Anti-Jk[b]				
SC I Jk(b+)	2+	2+	2+	1+
SC II Jk(b-)	0	0	0	0
Sample 272594 / Anti-c				
SC I c-	0	0	0	0
SCII c+	2+	2+	2+	2+
Sample 756581 / Anti-S				
SC I S+	2+	2+	2+	1+
SCII S+	2+	3+	2+	1+
Sample 328484 / AB Plasma				
SC I	0	0	0	0
SC II	0	0	0	0

SUMMARY OF RESULTS

Each sample from the Quotient ALBAcheck® Competency Testing Kit gave expected results in all methods used for antibody screening. Reaction strength varied between methods by no more than two grades. A variation of two grades is not unexpected when testing is performed using different enhancement solutions, or no enhancement, in manual tube testing, and when testing is performed using CAT (Gel) technique. As defined in our protocol, a two-reaction-grade difference is acceptable for comparison of methods for antibody screening.

The alloantibody specificities identified by our antibody identification testing matched those specificities provided for all antibody positive samples. The alloantibody (ies) in each test kit sample reacted with all of the corresponding antigen positive cells. There were no non-specific reactions. The AB plasma sample was non-reactive by all red cell antibody screening methods, as expected.

The identity of alloantibodies is provided to managers only via website, so specificities were unavailable to the technologist, ensuring unbiased test performance. For this lot of the Quotient ALBAcheck® Competency Testing Kit, antibody specificities included Anti-D, Anti-E, Anti-c, Anti-Jk[b], Anti-S, Anti-Fy[a] and Anti-K, as single or multiple specificities.

CONCLUSION

The Quotient ALBAcheck® Competency Testing Kit provides plasma samples with a variety of clinically significant polyclonal antibodies, validated for use by CAT (Gel) and multiple manual tube test methods. The kit outdates one year from the production date allowing testing over several months if needed. The test kit plasma samples provide a source of readily available, clinically significant alloantibodies with specific and reliable reactivity, validated by an independent source.

Incorporating the Quotient ALBAcheck® Competency Testing Kit into our protocol simplified our challenges for comparison of red cell antibody screen test methods. Use of the kit eliminated many variables related to the antibody positive sample, and proved to be a simple and convenient solution for complying with CAP TRM.31450 Comparability of Methods.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Medicare, Medicaid and CLIA programs; Fed Register. 2003(Jan 24):5236 [42CFR493.1281(a)]

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