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HBS Validation and Competency Kit

Intended Use:
The HBS Validation and Competency Kit is intended for use in method validation and competency testing for manual, automated and/or semi-automated blood typing, antibody detection/identification, and compatibility testing systems.

Summary and Explanation:
To ensure the accuracy of test systems, it is essential to validate the system before operational use. Validation should include testing of an appropriate number of samples for any assays performed with the new method in parallel with the current method in use. To ensure competency of testing personnel, blinded samples should be provided to technologists at regular intervals for evaluation.

The HBS Validation and Competency Kit provides simulated plasma samples representing a variety of ABO types in addition to both positive and negative indirect antiglobulin test (IAT) results. Also provided are instructions for selecting donor red cells for use in conjunction with the kit. The samples serve as material to validate the blood typing, antibody detection and identification, and compatibility testing capabilities of test systems and testing technologists.

Principle of the Procedure:
When used for validation, HBS Validation and Competency Kit samples are intended to be tested with the user's current testing method in parallel with the test method being validated to perform correlation studies when a change in test methodology is implemented.

When used for competency, HBS Validation and Competency Kit samples are intended to be used as blind samples to demonstrate technical competency in ABO typing, antibody screening and identification, and compatibility testing.

Reagent Description:

The HBS Validation and Competency Kit is provided as a set of ten vials, each containing simulated plasma samples. The samples represent an assortment of ABO types and may also contain clinically significant IgG antibodies which demonstrate reactivity in the indirect antiglobulin phase of antibody detection/identification tests.

HBS Validation and Competency Kit samples are prepared using monoclonal antibodies and bovine serum albumin and are supplied terminally filtered. This kit does not contain human source materials.

HBS Validation and Competency Kit samples have been optimized for use without further dilution or additions. Do not dilute or otherwise alter the kit specimens.

The format for the expiration date is expressed as YYYY-MM-DD (year-month-day). Lot number and expiration date information appears on the vial.

The specification of each sample is as follows:

Sample	Specification
1	ABO = O Antibody ID = Anti-D
2	ABO = A Antibody ID = Anti-E
3	ABO = AB Antibody ID = Anti-c (small)
4	ABO = A Antibody ID = Anti-K
5	ABO = O Antibody ID = Anti-Fy^a
6	ABO = B Antibody ID = Anti-S
7	ABO = AB Antibody ID = Anti-s (small)
8	ABO = A Antibody ID = Anti-D, Anti-K
9	ABO = O Antibody ID = Negative
10	ABO = B Antibody ID = Negative

Precautions:
1. This reagent contains 0.1% (w/v) sodium azide which is below the national and international regulatory thresholds and when used under normal condition is not chemically hazardous. If this reagent is discarded in the sink, flush with large volumes of water to prevent the buildup of azide.
2. This reagent is prepared using bovine albumin that is either USDA approved or from sources where origin information is available. The donor animals have been inspected and certified disease free and are deemed to have a low TSE (Transmissible Spongiform Encephalopathy) risk.
3. For in-vitro use only. These materials are not for use in diagnostic procedures.
4. Kit samples should be clear. Turbidity may indicate bacterial contamination. The product should not be used if a precipitate, fibrin gel or particles are present.

Storage:
Store the opened/unopened product at 2-8˚C until the expiry date detailed on the product label. Do not use past the expiration date. Failure to store the product as described may result in an accelerated loss of reactivity.

Procedure:
Materials Provided
HBS Validation and Competency Kit

Materials Required But Not Provided
Segments from RBC donor units

Recommended Technique:
1. Method validation should be performed according to the user's standard operating procedure.
2. When using automated/semi-automated instruments, follow the procedures contained in the operator manual.
3. When using manual systems, follow the reagent manufacturer's Instructions for Use.

Preparation of Donor Samples for Crossmatch Testing:
1. Donor segments should be prepared according to the operator manual provided by the device manufacturer or the user's standard operating procedure.
2. Choose donor red blood cells for ABO or compatibility testing according to the following chart:

Sample	For Forward Typing Select:	For ABO INCOMPATIBLE Crossmatch Select:	For AHG INCOMPATIBLE Crossmatch Select:	For ABO COMPATIBLE Crossmatch Select:	For AHG COMPATIBLE Crossmatch Select:
1	O	A, B, or AB	Rh (D) Positive	O	Rh (D) Negative
2	A	B or AB	E Positive	A or O	E Negative
3	AB	ABO incompatibility not expected	c (small) Positive	Any	c (small) negative
4	A	B or AB	K Positive	A or O	K Negative
5	O	A, B, or AB	Fya Positive	O	Fya Negative
6	B	A or AB	S Positive	B or O	S Negative
7	AB	ABO incompatibility not expected	s (small) Positive	Any	s (small) Negative
8	A	B or AB	Rh (D) and/or K Positive	A or O	Rh (D) **and** K negative
9	O	A, B, or AB	N/A	O	N/A
10	B	A or AB	N/A	B or O	N/A

Performance Limitations:

1. False reactivity can occur due to improper storage, contamination of test material or reagents used in testing, improper test performance, or failure to add reagents.
2. Refer to the operator manual provided by the device manufacturer for other limitations of the test system that may cause unexpected false positive or negative reactions.

Quality Control:

Refer to the operator manual provided by the device manufacturer for quality control requirements.

Interpretation of Results:

Refer to the operator manual provided by the device manufacturer for interpretation of results.

Specific Performance Characteristics:

Prior to release, each lot of HBS Validation Kit is tested to ensure suitable reactivity and results (positive and negative) when testing is performed by the following methodologies: Test tube, column agglutination technology (CAT) and solid phase red cell adherence (SPRCA).

No FDA standard of potency exists for this product.

For Technical Support, call Hemo bioscience at 1-866-332-2835.

Bibliography:

1. Butch, SH. Automation in the Transfusion Service. *Immunohematology*. 2008;24:86–92.
2. Wayne, PA. Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline. CLSI document I/LA33-A.: Clinical and Laboratory Standards Institute; 2009.
3. Roback, J.D., ed. Technical Manual. 17th ed. Bethesda, MD: AABB, 2011.

Glossary of Symbols:

Symbol	Definition
	Batch code
	Manufacturer
	Temperature limitation
	Consult instructions for use.
	Use by YYYY-MM-DD
	Caution, consult documents.