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| Department: | Laboratory and Blood Bank | | |
| Document: | Internal Policy and Procedure | | |
| Title: | Quality Control of Reagents of the Gel Microtyping System | | |
| Applies To: | All Blood Bank Staff | | |
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1. PURPOSE:

- 1.1 Ensure the reliability of the blood bank serological test results.

2. DEFINITIONS:

- 2.1 "**MBC**" (**method-based control**) refers to system control that uses a sample of whole blood or a manufactured substitute to perform quality control on the system.

3. POLICY:

- 3.1 Monitoring the quality of reagents in blood bank is important for the reliability of the test results and benefit of patients.
- 3.2 The control sample should always have the same characteristics as a patient sample and therefore be treated identically.
- 3.3 The same general policies and responsibilities for "quality control of serological blood bank reagents" apply.

4. PROCEDURE:

- 4.1 Testing reagents against known samples is an accepted method of daily quality assurance in blood bank:
 - 4.1.1 If expected results are observed, this means the quality of reagents, procedures and equipment are good enough and test results are good enough and may be reported.
 - 4.1.2 If unexpected results are observed, the problem has to be resolved before reporting the results.
- 4.2 The control sample should always have the same characteristics as a patient sample and therefore be treated identically.
- 4.3 For Gel Cards:
 - 4.3.1 Do not use cards that show signs of drying. A liquid layer should appear on top of the gel in each microtube.
 - 4.3.2 Do not use cards in which the microtubes show discoloration, bubbles or crystals.
 - 4.3.3 To confirm the specificity and reactivity of the IgG gel card the manufacturer recommends that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red cell. Reactivity shall be present in the positive specimen only.
- 4.4 There are a number of QC reagents that could be used. As the control sample should always have the same characteristics as a patient sample, QC samples from another manufacturer might be used in case of deficient supply.
- 4.5 DiaMed Basic Q.C. and IH-QC Modular System can be used for ID-system. ORTHO CONFIDENCE™ WB could be used for ORTHO CLINICAL DIAGNOSTICS SYSTEMS.
 - 4.5.1 "DiaMed Basic Q.C." is designed to control manual techniques and also the instruments used for blood group typing, reverse grouping and antibody screening by providing blood of known blood groups and with known antibodies. Those reagents have been validated for use on ID-systems.

- tubes (IH-QC 1 to 8) containing human red blood cell suspensions to be combined according to your needs. Those reagents have been validated for use on ID-systems.
- 4.5.3 "ORTHO CONFIDENCE™ WB" A Single QC System for the ORTHO BioVue® System and ORTHO Vision® Analyzer. This reagent has been validated for use on those systems.
- 4.6 **Preparation of quality control samples:**
- 4.6.1 Allow the test material to reach room temperature (18-25 °C) before use.
- 4.6.2 The tubes should be centrifuged as with regular patient samples (eg. for 10 minutes at 1500 g).
- 4.7 **Test procedure:**
- 4.7.1 Treat the quality control samples in exactly the same way as patient samples. After use replace the samples in the refrigerator.
- 4.8 **For DiaMed Basic Q.C.:**
- 4.8.1 Performance Characteristics:
- 4.8.1.1 If the results do not correspond to the data in the box insert, the test methods, working procedure, automated equipment/instruments and materials used should be checked immediately. Repeat the controls after making appropriate corrections.
- 4.8.1.2 Different batches of "DiaMed Basic Q.C." can give different reaction strengths, especially in the antibody screening procedures.
- 4.8.1.3 Each cell sample is shown to have a negative DAT.
- 4.8.2 Limitations:
- 4.8.2.1 Do not use when the reagent red cells are obviously discoloured or haemolysed.
- 4.8.2.2 Anti-D in Sample 1 may give a negative reaction (When tested versus red cells with low numbers of D antigens per erythrocyte,).
- 4.8.3 Remarks:
- 4.8.3.1 All QC products are standardized at 0.05 IU for Anti-D which conforms to the minimum international requirements.
- 4.8.3.2 If the number of D antigen sites per red cell is low, the result could be negative as the antibody may be below the limit of detection.
- 4.9 **For IH-QC Modular System:**
- 4.9.1 Performance Characteristics:
- 4.9.1.1 If the results do not correspond to the data in the box insert, the test methods, working procedure, automated equipment/instruments and materials used should be checked immediately. Repeat the controls after making appropriate corrections.
- 4.9.1.2 Different batches of antibody screening and identification red blood cells can give different reaction strengths with IH-QC1/IH-QC2/IH-QC3/IH-QC4.
- 4.9.2 Limitations: Erroneous and abnormal results may be caused by:
- 4.9.2.1 Non respect of the intended use or shelf life or stability after opening.
- 4.9.2.2 Bacterial or chemical contamination of the IH-QC Modular System.
- 4.10 **For ORTHO CONFIDENCE™ WB:**
- 4.10.1 Performance Characteristics:
- 4.10.1.1 When properly stored and used according to standard procedures, these reagents will demonstrate the appropriate antigens / antibodies specified in the reagent description.
- 4.10.1.2 Each cell sample is shown to have a negative direct antiglobulin test.
- 4.10.2 Interpretation: The following table illustrates the expected results in tests with ORTHO CONFIDENCE™ WB Quality Control Kit and routine blood bank reagents.

| 4.10.2.1 | Reagent Under Test | Vial 1 | Vial 2 | Vial 3 | Vial 4 |
|----------|---------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | | Expected Test Results | Expected Test Results | Expected Test Results | Expected Test Results |
| | Anti-A | + | 0 | + | 0 |
| | Anti-B | + | 0 | 0 | + |
| | Anti-A,B | + | 0 | + | + |
| | Anti-D | + | + | + | 0 |
| | A1 cells | 0 | + | 0 | + |
| | A2 cells | 0 | + | 0 | + |
| | B cells | 0 | + | + | 0 |
| | O cells | 0 | 0 | 0 | 0 |
| | Screening cell 1 (R1R1) | 0 | 0 | * | + |
| | Screening cell 2 (R2R2) | 0 | + | * | + |
| | Screening cell 3 (rr) | 0 | + | * | 0 |
| | Anti-C | + | + | 0 | 0 |
| | Anti-E | + | 0 | + | 0 |
| | Anti-c | + | 0 | + | + |
| | Anti-e | + | + | 0 | + |
| | Anti-K (with vial 2 only) | - | + | - | 0 |

(*) depends on antigen configuration.

4.10.2.2 Discrepant results must be investigated further.

4.10.3 Limitations:

4.10.3.1 ORTHO CONFIDENCE™ WB Quality Control Kit is designed to be tested with reagents that have not been diluted.

4.10.3.2 Improper techniques may invalidate the results obtained with this product.

4.10.3.3 False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, and omission of test reagents.

4.10.3.4 Under certain circumstances, the anti-c specificity present in the plasma of vial 2 may react at room temperature with Affirmagen O cells when tested in conjunction with ORTHO BioVue® System Reverse Diluent cassettes, generating an unexpected weak positive reaction.

4.11 Interpretation of the results:

4.11.1 Use the following symbols:

4.11.1.1 **S**: Satisfactory

4.11.1.2 **N**: Not Satisfactory

4.11.1.3 **nt** = not tested

4.11.2 If the reactions and results are not satisfactory, the working procedures should be verified along with routine test methods and materials used.

4.11.3 The necessary corrective action should be taken and the tests repeated.

4.12 Quality control for ORTHO VISION® Analyzer:

4.12.1 The ORTHO Confidence™ WB is the MBC quality control set used on ORTHO VISION™ Analyzer.

4.12.1.1 User-defined QC samples could be used.

4.12.2 Quality control lot samples should be pre-defined on the system. You can create a new lot or change it. You can also delete the expired lots (refer to Quick Guide ORTHO VISION® Analyzer).

- 4.12.3 Quality Control is assigned to a profile.
- 4.12.4 To Process Quality Controls (MBC):
 - 4.12.4.1 Load the four samples of ORTHO CONFIDENCE™ WB Quality Control:
 - 4.12.4.1.1 Select the "Samples" menu to display the Samples screen.
 - 4.12.4.1.2 Select a rack on the diagram and touch the "Load/Unload" action button. The wizard lets you open the Load Station Door.
 - 4.12.4.1.3 Load the samples rack with uncapped 4 samples.
 - 4.12.4.1.4 Close the Load Station Door. The system scans the contents of the sample racks and updates the information on the Samples screen.
 - 4.12.4.2 Touch the "QC" menu button.
 - 4.12.4.3 Select the desired profile with associated quality control MBC and select "Run QC Job" button.
 - 4.12.4.4 Once the job finished, the system gives QC status either accepted or failed. This will be shown on results.
- 4.12.5 Notes:
 - 4.12.5.1 QC result modification:
 - 4.12.5.1.1 If a column grade for a QC test is resulting in a failed QC, it is possible for the user to edit the column grade.
 - 4.12.5.1.2 The system will then recalculate the new column grades and re-evaluate the QC status.
 - 4.12.5.1.3 Note: the user cannot edit the status of the QC test, but changes to the column grades may cause the system to re-evaluate the QC status.
 - 4.12.5.1.4 This modification is done in the "Results" menu.
 - 4.12.5.1.5 See the section "Edit a Column Grade (Modify)" in the "Quick Guide ORTHO VISION® Analyzer".
 - 4.12.5.2 QC History: The system supports a QC MBC history report. User can print or export the new report by selecting a date range or choosing one of several predetermined date selections.
 - 4.12.5.2.1 Touch the "QC" menu button.
 - 4.12.5.2.2 Select the profile with associated quality control MBC.
 - 4.12.5.2.3 Select "Show QC History Report" button on the bottom of the screen
 - 4.12.5.2.4 Select a date range for the report: Start Date and End Date or Select a data range in the Presets.
 - 4.12.5.2.5 Press "Yes".
 - 4.12.5.2.6 The report can be printed out, exported or saved in electronic format.
 - 4.12.5.2.7 Note: if the selection is covering a long period, the report may need few minutes to be generated.

5. MATERIALS AND EQUIPMENT:

5.1 Forms and Records:

- 5.2.1 Daily Quality Control of Gel Microtyping System Form

5.2 Materials and Equipment:

- 5.2.1 DiaMed Basic Q.C.: DiaMed Basic Q.C." contains 2 complete samples, each consisting of 8 tubes containing 5 ml of a human whole blood suspension (Hct 15% ±2), bovine serum albumin and added antibodies as appropriate. Once opened, each sample tube may be used for a maximum of 7 days.
 - 5.2.1.1 Sample 1: group A (ABO:1,-2), RhD negative ccee (RH:-1,-2,-3,4,5), K positive (KEL:1) sample containing anti-B (anti-ABO2) and anti-D (anti-RH1) (0.05 IU/ml).
 - 5.2.1.2 Sample 2: group B (ABO:-1,2), RhD positive CcEe (RH:1,2,3,4,5), K negative (KEL:-1) sample containing anti-A (anti-ABO1) and anti-Fy^a (anti-FY1).

- 5.2.2 IH-QC Modular System: It consists of 8 tubes (IH-QC 1 to 8). Each contains contain 6 ml of a human red blood cell suspension, bovine serum albumin and added antibodies as appropriate. Once opened, each sample tube may be used for a maximum of 7 days.
- 5.2.2.1 IH-QC-1: A1 [ABO:1,-2,3,4], ddccee (rr) Cw- [RH:-1,-2,-3,4,5,-8], K+ [KEL:1] sample containing Anti-B [Anti-ABO2], Anti-D [Anti-RH1] (0.05 ≤ IU/ml). DAT: negative.
- 5.2.2.2 IH-QC-2: B [ABO:-1,2,3], DCcEe (R1R2) Cw- [RH:1,2,3,4,5,-8], K- [KEL:-1] sample containing Anti-A [Anti-ABO1], Anti-Fya [Anti-FY1]. DAT: negative.
- 5.2.2.3 IH-QC-3: AB [ABO:1,2,3], DCcEe (R1R1) Cw- [RH:1,2,-3,-4,5,-8], K- [KEL:-1] sample containing Anti-c [Anti-RH4]. DAT: negative.
- 5.2.2.4 IH-QC-4: O [ABO:-1,-2,-3], DccEE (R2R2) Cw- [RH:1,-2,3,4,-5,-8], K- [KEL:-1] sample containing Anti-A and Anti-B [Anti-ABO1 and Anti-ABO2], Anti-K [Anti-KEL1]. DAT: negative.
- 5.2.2.5 IH-QC-5: A2 [ABO:1,-2,3,-4], DCcee (R1r) Cw- [RH:1,2,-3,4,5,-8], K- [KEL:-1] sample containing Anti-B [Anti-ABO2]. DAT: negative.
- 5.2.2.6 IH-QC-6: Weak D [RH:W1]. DAT: negative.
- 5.2.2.7 IH-QC-7: DAT: positive (IgG).
- 5.2.2.8 IH-QC-8: DAT: positive (C3b (c/d)).
- 5.2.3 ORTHO CONFIDENCE™ WB: four vials of simulated whole blood of a human red blood cell suspension, and added antibodies as appropriate.
- 5.2.3.1 Vial 1 - Group A₁B D+C+E+c+e+ (R₁R₂) .
- 5.2.3.2 Vial 2 - Group O D+C+E-c-e+ (R₁R₁) K+, anti-A, anti-B, anti-c
- 5.2.3.3 Vial 3 - Group A D+C-E+c+e- (R₂R₂) Fy(a-), anti-B, anti-Fy_a.
- 5.2.3.4 Vial 4 - Group B D-C-E-c+e+ (rr) K-, anti-A, anti-D (concentration of approximately 0.1 IU/mL)
- 5.2.4 Material and equipment for the routine test procedures with each gel microtyping system.

6. RESPONSIBILITIES:

- 6.1 Blood bank staff in the pre-transfusion areas.

7. APPENDICES:

- 7.1 N/A

8. REFERENCES:

- 8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.
- 8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.
- 8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.
- 8.4 AABB Technical manual, 18th edition, 2014.
- 8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.
- 8.6 Diamed manufacture catalogue. 2013 .
- 8.7 DiaMed Basic Q.C. insert, B009948, 04.18.
- 8.8 IH-QC Modular System insert, B009321, 10.18
- 8.9 ORTHO CONFIDENCE™ WB Simulated Whole Blood Quality Control Kit, Instructions For Use, Pub. No. J39796_EN, Version 4.0, 2017-02-17
- 8.10 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA

9. APPROVALS:

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