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| **Performing Daily QC for IH-Reader or Manual System** | | | | | | | |
| **Purpose** | This procedure provides instructions for performing quality control testing on blood bank reagents for daily use on the IH-Reader 24 or manual system | | | | | | |
| **Policy Statements** | * Blood Bank reagents must be tested for potency and specificity on each day of use. * News lots of reagents must be tested before or concurrently with first use. * Quality control testing should be performed after service and/or repair of the analyzer and after reading calibration * Quality control testing will be performed according to the manufacture’s recommendations. * All Blood Bank reagents in use will be visually checked for expiration date and appearance prior to quality control testing and before and testing use. Any reagent that has expired or shows evidence of contamination or deterioration (turbidity or hemolysis) will be discard as biohazard waste. * All QC records will be printed and reviewed and place in the reagent QC book * All quality controls must fall within the “acceptable results”. If test results differ from the “acceptable results”, then the Out of Control Plan must be implemented. * The Transfusion Service Technical Specialist or Medical Director will review quality control. * Blood bank reagents should be stored according to the manufacture’s recommendations | | | | | | |
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| **Materials** | **Equipment** | | | **Reagents** | | | **Supplies** |
| * IH-Incubator L * IH-Reader 24 * IH-Centrifuge L | | | * Solidscreen II Negative Control * IH-Basic QC * IH-Cell I, II * IH-Cell A1, B * IH-LISS * IH-Card ABO/D(DVI-)+Rev A1,B * IH-AHG Anti-IgG * IH-Card ABD(DVI+) * IH-Card ABD(DVI-) * IH-Anti-D Blend | | | * MLA pipette * Pipette tips * 10 x 75mm |
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| **Procedure** |  | | | | | | |
|  | **Step** | Action | | | | | |
|  | 1 | The ‘QC’ tab of IH-Com Client displays the list of all reagents that require QC. The current lot of each reagent will be listed along with the expiration date and time of the QC for that reagent. If QC has expired or was unsuccessful, a red flashing symbol will appear beside that reagent and the QC tab itself will flash red. | | | | | |
|  | 2 | The QC tab will flash red 2 hours prior to QC expiring. Reagents will have an exclamation mark in a yellow triangle. QC is still valid. | | | | | |
| Entering New Lot QC | 3 | If a new lot of Bio-Rad QC samples will be put in to use:   1. Open the QC tab in IH-Com. Select the ‘Control Samples’ button. 2. Select ‘New Lot’. 3. Scan the barcode on the Bio-Rad QC samples. 4. Verify and/or enter the correct target values and expiration date. 5. Select ‘Save. | | | | | |
| QC ABO/Rh Antibody Screen and Weak D | 5 | IH-Basic QC and Solidscreen II negative for ABO/Rh, Antibody Screen and Weak D:   1. IH-Basic QC contains 8 vials    1. 4 vials of Sample 1       1. RhD negative, K positive and containing Anti-B and Anti-D    2. 4 Vials of Sample 2       1. RhD positive, K negative and containing Anti-A and Anti-Fya    3. Opened tubes have a shelf-life of 10 days, or the original expiration date, whichever is shorter. 2. Solidscreen II Negative Control: | | | | | |
| Requesting Controls | 7 | Requesting Controls:   1. Open the ‘QC tab in IH-Com.      1. Select the ‘Order Controls’ button      1. Ensure the desired control tests have a checkmark in the left column. If not, click on the box to place a checkmark. 2. Scan each control sample. Once scanned, all test for that control sample will be highlighted with a green background. 3. Once all control samples are scanned, select the ‘Order’ button. | | | | | |
|  | 8 | Select the Manual Work tab. | | | | | |
|  | 9 | Select the Assign Cards button. Scan the reagents to be used for QC, if needed. Scan the gel cards need for QC. | | | | | |
|  | 10 | Close the Manual Work window by selecting the Close button. | | | | | |
|  | 11 | Pipet and process the QC sample gel cards;   1. 2 IH-Card ABO/D(DVI-)+Rev A1,B    1. IH-Basic Sample 1       1. Make 1% dilution of packed cells-add 50µL into wells A, B, DVI-, and ctl       2. Add 50µL of A1 and B cells into corresponding wells then add 50µL of QC plasma    2. IH-Basic Sample 2       1. Make 1% dilution of packed cells-add 50µL into wells A, B, DVI-, and ctl.       2. Add 50µL of A1 and B cells into corresponding wells then add 50µL of QC plasma   IH-Card ABO/D(DVI-)+Rev A1,B 48 cards #813111100 | Bio-Rad   1. 1 IH-Card ABD(DVI+)    1. IH-Basic Sample 1       1. Make 1% dilution of packed cells-add 50µL into wells A, B, DVI+    2. IH-Basic Sample 2       1. Make 1% dilution of packed cells-add 50µL into wells A, B, DVI+   ABD DVI plus Confirmation | Bio-Rad   1. 1 IH-Card ABD(DVI-)    1. IH-Basic Sample 1       1. Make 1% dilution of packed cells-add 50µL into wells A, B, DVI-    2. IH-Basic Sample 2       1. Make 1% dilution of packed cells-add 50µL into wells A, B, DVI-   IH-Card ABD(DVI-)-Conf 48 cards #813181100 | Bio-Rad   1. 1 IH-AHG Anti-IgG card (Positive and Negative Antibody Screen)    1. IH-Basic Sample 1       1. Add 50µL of IH-Cell I and II to two wells and add 25µL of QC plasma    2. Solidscreen II Negative Control       1. Add 50µL of IH-Cell I and II to two wells and add 25µL of QC plasma   IH-Card AHG Anti-IgG 288 cards #813422100 | Bio-Rad   1. 1 IH-AHG Anti-IgG card **(Weak D –as needed)**    1. IH-Basic Sample 1       1. Make 1% dilution of packed cells-add 50µL into wells to one well       2. Add 25µL of IH-Anti-D into corresponding well    2. IH-Basic Sample 2       1. Make 1% dilution of packed cells-add 50µL into wells to one well       2. Add 25µL of IH-Anti-D into corresponding well   IH-Card AHG Anti-IgG 288 cards #813422100 | Bio-Rad | | | | | |
|  | 12 | Pace the IgG cards into the IH-Incubator L for 15 minutes but no longer than 20 minutes. After the incubation follow steps 13-16 | | | | | |
|  | 13 | Place ABO/Rh cards into the IH-Reader 24.   1. If lid is not open, click on      1. Load cards into the centrifuge head making sure the head is balanced and the barcode is facing to the next position. 2. Close lid | | | | | |
|  | 14 | Click the centirifuge and read button. Make sure the centrigue starts spinning before walking away | | | | | |
|  | 15 | After testing is complete, select the ‘Results’ tab in IH-Com.   1. Select the ‘To Read’ tab 2. Review results of the control samples. If acceptable, select ‘Accept All’ then ‘Save’. Repeat for each control sample. | | | | | |
|  | 16 | Select the ‘QC’ tab and then select the ‘Print’ button to print a Daily Quality Control Report. Alternatively, select ‘Print’ from the menu bar and then ‘Results and Protocols’. Chose the ‘Quality Control’ tab and select the date to print. | | | | | |
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| Manual QC | 1 | Follow steps 11-12 in IH-Reader 24 QC to perform manual QC. | | | | | |
|  | 2 | Record QC on TSf 18.4.1 | | | | | |
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| **Interpretation** | **Positive test**-Agglutination of red cells  **Negative test**- No agglutination of red cells | | | | | | |
| **Limitations** | 1. False negative or positive reactions can occur due to contamination, improper storage, improper test performance or failure to add reagents. The cause(s) of a failure should be investigated and resolved. 2. Reaction strength using the same method and lot of red cells and anti-sera should be comparable. A significant decrease in the reaction strength should be investigated. | | | | | | |
| **References** | 1. IH-Com User Manual NA V1.2-02/2021, Chapter C, Section 4.8 and 4.10 2. Product Insert, IH-Basic QC, Bio-Rad Medical Diagnostic, current version 3. Product Insert, Solidscreen II Negative Control, Bio-Rad Medical Diagnostic, current version | | | | | | |
| **Approval**  **Workflow** | Transfusion Service/Lab Director | | | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | | **Effective Date:** | **Summary of Revisions** | |
| 1 | | S. Cassidy | | 02/17/2023 | Initial Version | |