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ORTHO VISION Analyzer Manual Card Review

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

The ORTHO VISION™ has been configured to send gel cards to the service rack to help the technologists identify those gel cards that need to be reviewed before results are sent across the interface to the laboratory information system (LIS). The purpose of this document is to provide guidelines for extracting, identifying, and managing gel cards that are sent to the Manual Review Rack by the ORTHO VISION™.

II. POLICY STATEMENT:

Any gel cards sent to the Manual Review Rack by the ORTHO VISION™ must be reviewed before results are sent across the interface to the Blood Bank computer system. The ORTHO VISION™ sends gel cards to the Manual Review Rack for several reasons, including but not limited to:

A. ABO/Rh cards with a 1+ or 2+ graded reaction in the forward ABO typing, or a 1+ graded reaction in the reverse typing.

B. ABO/Rh cards with a 1+, 2+, or 3+ graded reaction in the Rh(D) typing.

C. Antibody screen (ABSC) cards with any positive graded reaction.

D. Any gel card with a well discrepancy; see header IV, letter D *Gel Cards with Well Discrepancies* in this document.

E. Any gel card with a positive crossmatch of any strength.

F. All cards will be sent to the manual review rack if a required maintenance is due but has not been performed.

G. Gel cards that the ORTHO VISION™ cannot read; the *Card Reader Error* warning message appears.

H. All panel cards.

III. DEFINITIONS / ACRONYMS:

A. **LIS:** Laboratory information system.

B. **MT Lead:** Medical Technologist Lead.

C. **Designee:** A medical technologist with increased computer access in the Blood Bank computer system necessary to override the pre-determined results logic table of a test.

D. **Manual Review Rack:** Also referred to by the ORTHO VISION™ as the service rack.

IV. INSTRUCTIONS:

A. **Technologist Must Review / Modify Graded Reactions of all Gel Cards Sent to the Manual Review Rack.**

1. All gel cards that are sent to the Manual Review rack shall be reviewed by a technologist; the gel card itself shall be visually reviewed. If the technologist agrees with the graded reaction they may accept the result and send to the LIS. If the technologist grades a reaction differently than the ORTHO VISION™, then they shall modify the graded reaction in the ORTHO VISION™ accordingly before the results are sent across the interface to Soft. Reactions are graded as described in *Reading, Grading, and Recording Test Reactions*.
2. Note: Reaction grading can only be modified **once** on the ORTHO VISION™, it is unable to be modified again. If addition modification is required, you must modify the reaction grading in the Blood Bank computer system prior to verifying the results.

B. **Valid Graded Reactions and Interpretations.**

1. Based on Blood Bank procedures, graded ABO and Rh(D) reactions must be valid in order to interpret the results. The graded reactions must be of specific strengths to be considered valid by the Blood Bank procedures. Note that the ORTHO VISION™, Blood Bank computer system, and the Blood Bank procedures interpret results differently. All tests must be interpreted from the actual gel card based on the Blood Bank procedures, not necessarily how the Blood Bank computer system or the ORTHO VISION™ interprets them.

C. **Current type does not Match Historical Type.**

1. Note that the ORTHO VISION™ identifies a sample with only a specimen ID number. If the current type does not match the historical type, the ORTHO VISION™ will not know this or warn of this and the sample will not be sent to the service. The warning message will not appear until the technologist attempts to verify the results in the Blood Bank computer system. This warning message must be investigated as described in *Resolution of ABO and Rh(D) Discrepancies*.

D. **Gel Cards with Positive Crossmatch Results.**

1. The ORTHO VISION™ is configured to send gel cards with any positive crossmatch reaction strength to the Manual Review Rack. As with all gel cards that are sent to the service rack, the graded reactions shall be reviewed by a medical technologist. If the technologist grades a reaction differently than the ORTHO VISION™ then the technologist shall modify the graded reaction in the ORTHO VISION™ accordingly before the results are sent across the interface to the Blood Bank computer system. Refer also to *Investigation of Incompatible Crossmatches.*

E. **ABO/Rh Gel Cards that the ORTHO VISION™ Interprets as NRD (No Results Determined).**

ABO Example						
Anti-A	**Anti-B**	**Anti-D**	**Control**	**A Cells**	**B Cells**	**Interpretation**
0	0	4+	0	1+	0	? Pos
Rh(D) Example						
Anti-A	**Anti-B**	**Anti-D**	**Control**	**A Cells**	**B Cells**	**Interpretation**
0	0	4+	1+	4+	4+	O ?

1. After the technologist extracts the gel card from the Manual Review Rack, the technologist will review the gel cards and, if applicable, modify the results.
2. The technologist will attempt to resolve the ABO/Rh discrepancy as described in *Resolution of ABO and Rh(D) Discrepancies*.
3. If the technologist is unable to resolve the discrepancy, then a supervisor, MT Lead or designee who will interpret the results as GND or RND.
4. If the technologist is able to resolve the discrepancy, then:
    a. Print a copy of the results by Show Order Report.
    b. Reject the results on the ORTHO VISION™.
    c. The printed copy of results from the ORTHO VISION™ will be used to document the results in the Blood Bank computer system.

F. **ABO/Rh Gel Cards with Graded Reactions that are Interpreted by the ORTHO VISION™, but that should not be Interpreted Based on Blood Bank Procedures.**

ABO Example						
Anti-A	**Anti-B**	**Anti-D**	**Control**	**A Cells**	**B Cells**	**Interpretation**
1+	0	4+	0	0	1+	A Pos
Rh(D) Example (see note below)*						
Anti-A	**Anti-B**	**Anti-D**	**Control**	**A Cells**	**B Cells**	**Interpretation**
0	0	2+	0	4+	4+	O Pos

1. Although considered invalid by the Blood Bank procedures, these results are interpreted by the ORTHO VISION™. The technologist should not send these results across the interface to the Blood Bank computer system.
   The technologist will:
    a. Print a copy of the results by Show Order Report.
    b. Reject the results on the ORTHO VISION™.
    c. Investigate the discrepancy as described in *Resolution of ABO and Rh(D) Discrepancies*.
    d. The Results by Show Order Report will be used to document the results in the Blood Bank computer system.
2. If the technologist is unable to resolve the discrepancy, or if the technologist does not have the required computer access to interpret the results in the Blood Bank computer system, a supervisor, MT Lead or designee who has this access will interpret the results as GND or RND.
3. Note: The Rh(D) Example, above:
    a. Based on *Resolution of Rh(D) Discrepancies*, the 2+ graded reaction for the Rh(D) is not a valid graded reaction. The ORTHO VISION™ will interpret this result as Rh pos, but the Blood Bank computer system will interpret this result as weak D pos. This Rh discrepancy must be investigated as described in *Resolution of Rh(D) Discrepancies*. Although the most likely cause for this 2+ reaction is that the patient is weak D or partial D positive, there are many other potential causes. Examples of other causes include recent Rh(D) dissimilar RBC transfusions, a bone marrow transplant, a mistyped sample, and a wrong blood in tube event (WBIT).

G. **Gel Cards with Mixed-Field Reactions.**

1. Mixed-field reactions are referred to as MF reactions by the ORTHO VISION™. MF reactions are considered a well discrepancy; however they can still be interfaced into the Blood Bank computer system. MF reactions may occur in patients who have been recently transfused; refer to *Resolution of ABO and Rh(D) Discrepancies for Recently Transfused Patients.*
    a. Accept the MF results on the ORTHO VISION™ and click "Send to LIS."
    b. Print a copy of the results by "Show Order Report" under the Results tab.
    c. Give the results to a supervisor, MT Lead or designee who has access to investigate the discrepancy.
    d. The results are interpreted as described in *Resolution of ABO and Rh(D) Discrepancies for Recently Transfused Patients*.

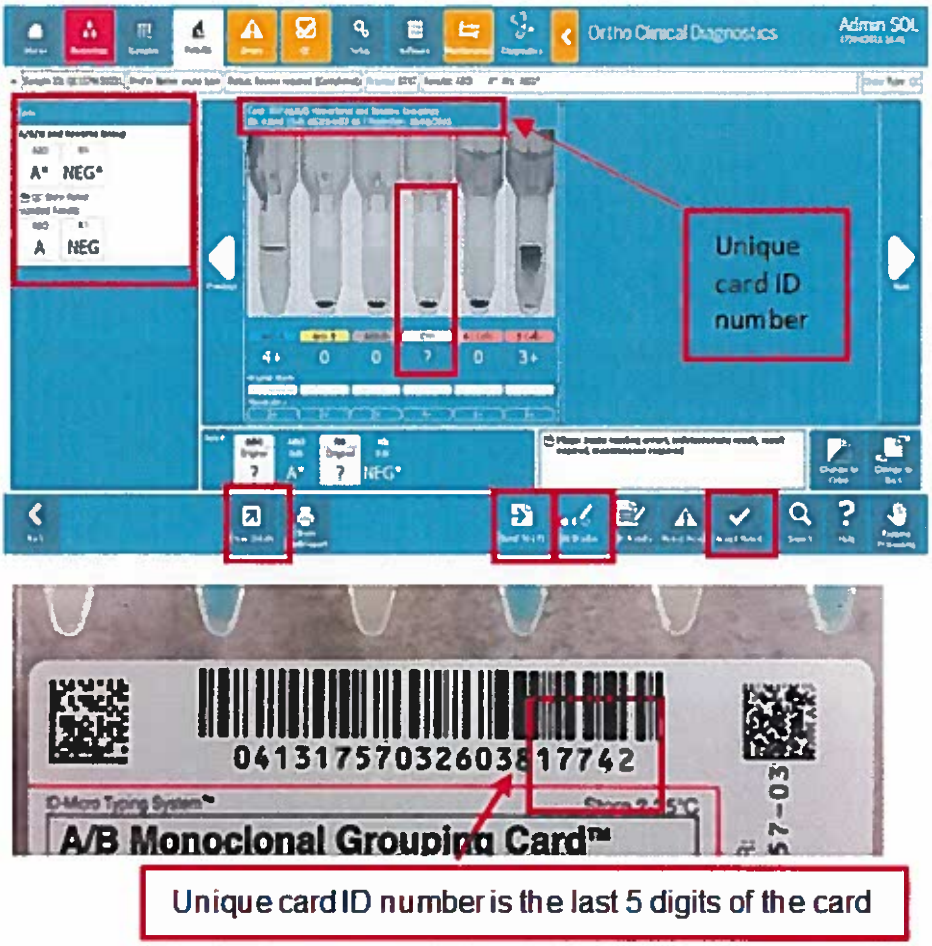
H. **Gel Cards with Well Discrepancies (Codes).**

1. The ORTHO VISION™ is configured to send gel cards with well discrepancies to the Manual Review Rack. Results with well discrepancies are not interpreted by ORTHO VISION™ and do not interface to the Blood Bank computer system.
    a. As with all gel cards that are sent to the Manual Review Rack, the graded reactions shall be reviewed by a medical technologist. If the technologist grades a reaction differently than the ORTHO VISION™ then the technologist shall modify the graded reaction in the ORTHO VISION™ accordingly.
    b. If the technologist is unable to resolve the discrepancy, or if the technologist does not have the required computer access to interpret the results in Soft, the technologist will print the Results by Show Order Report from the ORTHO VISION™ and submit it to a supervisor, MT Lead or designee who has this access.
    c. See attachment *ORTHO VISION™ Analyzer System Flags and Codes*, for a listing of codes along with the conditions and suggested actions.

V. PROCEDURE:

A. **To Change Results:**

1. Retrieve the card from the Manual Review Rack. Note that when opening the Dual Purpose Drawer, all cards that are in the Manual Review portion must be removed at that time.
    a. Resources.
    b. Manual Load Review.
    c. Load-Unload.
2. Edit the Reaction Grade.
    a. Touch Results.
    b. Select the test to be edited.
    c. Show Details.
    d. If there is more than one test ordered on that sample, Select Test box on left side of screen. Identify the card needed for review by matching unique card ID number to card ID number on the ORTHO VISION™ screen.



e. Touch Edit Grades.

f. Scan card barcode.

g. Select reaction grade to be edited.

h. Change the reaction strength. Note that all reactions are graded by inspecting the gel card, not using the ORTHO VISION™ screen.

i. Touch Next.

j. Add comment (if necessary).

k. Touch Next.

l. Input password.

m. Touch Confirm Password.

3. Accept the results.

   a. The results will not cross the interface to the LIS until they have been accepted.

4. Send the results to the LIS.

   a. If a Type & Screen is ordered on the specimen, both card results (the type and the antibody screen card) will need to be sent to the LIS.

5. Verify the results in the Blood Bank computer system.

B. **To Review Results That Don't Need Editing:**

1. Retrieve the card from Manual Review Rack. Note that when opening the Dual Purpose Drawer, all cards that are in the Manual Review portion must be removed at that time.
    a. Touch Resources.
    b. Touch Manual Load Review.
    c. Touch Load-Unload.
2. View the Reaction / Well.
    a. Touch Results.
    b. Select the test to be reviewed.
    c. Touch Show Details.
    d. If there is more than one test ordered on that sample, Select Test box on left side of screen.
    e. Identify the card needed for review by matching unique card ID number to card ID number on the ORTHO VISION™ screen.

    f. If there is agreement with the results in the well, touch accept.
    g. If there is non-agreement with the wells in question, edit the wells. See the *To Change Results* procedure section above.
3. Accept the results.
    a. The results will not cross the interface to the LIS until they have been accepted.
4. Send the results to the LIS.
    a. If a Type & Screen is ordered on the specimen, both card results (the type and the antibody screen card) will need to be sent to the LIS.
5. Verify the results in the Blood Bank computer system.

VI. REFERENCES:

A. AABB. (2020) *Standards for Blood Banks and Transfusion Services*. (32nd ed). AABB.

B. Cohn, C.S., Delaney, M, Johnson, S.T., Katz, L.M. (2020) *Technical Manual*.(19th ed.). AABB.

C. Ortho Clinical Diagnostics, Rochester, NY, Ortho Vision General Operator Training Manual, Publication J56102.

D. ORTHO VISION® Analyzer ID-MTS Gel Cards Reference Guide J40050.

E. ORTHO VISION® Analyzer ID-MTS Gel Cards Self-Service Customer Procedures Guide J40055ENNA.

F. ORTHO VISION® Analyzer Electronic Library, Software version 5.3.0.0.

G. Ortho Clinical Diagnostics, Rochester, NY, Electronic Publication number J56102.

H. ID-Micro Typing System® Implementation Guide 6902200.

Attachments

ORTHO VISION Analyzer System Flags and Codes (02/09/2021)

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	3/2/2021
	Vaishali Pansare: Chief, Pathology	3/2/2021
	Peter Millward: Chief, Pathology Service Line	3/2/2021
	Muhammad Arshad: Chief, Pathology	2/26/2021
	Craig Fletcher: System Med Dir, Blood Bank	2/25/2021
	Ryan Johnson: OUWB Clinical Faculty	2/24/2021
	John Pui: Chief, Pathology	2/24/2021
Policy and Forms Steering Committe (if needed)	Christopher Ferguson: Medical Technologist Lead	2/24/2021
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	2/24/2021
	Billie Ketelsen: Mgr Laboratory	2/24/2021
	Karrie Torgerson: Supv, Laboratory	2/17/2021
	Anji Miri: Supv, Laboratory	2/17/2021
	Michael Rasmussen: Supv, Laboratory	2/17/2021
	Teresa Lovins: Supv, Laboratory	2/17/2021
	Kelly Sartor: Supv, Laboratory	2/17/2021
	Christopher Ferguson: Medical Technologist Lead	2/17/2021

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

Beaumont HEALTH

Beaumont Laboratory
Transfusion Medicine

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

02/09/2021

Result Code	Definition	Column Interpretation	Conditions	Suggested Actions
U	Unknown	No Result Reported	The system received a result from the IMAGING SYSTEM that was not interpretable.	Rerun the test.
CNF	Column Not Found	If the correct location could not be ensured during the preprocessing check, the column will be marked as not usable; if the correct location could not be found during the post processing check the result is not reported.	The CARD IMAGING SYSTEM could not ensure the column was in the correct location.	If the correct location could not be ensured during the preprocessing check, clean any debris from the surface of the card and load the card into the SUPPLY DRAWER to be reused. If the correct location could not be found during the post processing check, rerun the test.
WLL	Wrong Liquid Level	No Results Reported	The IMAGING SYSTEM could not confirm that the correct volume of liquid is in the reaction chamber. One of the liquid additions may be missing.	Inspect the reaction chamber to determine if the liquid level is correct or not. A false error may be caused by a faint meniscus. If the liquid level is correct, manually read the column and edit the column result. If the liquid level is not correct, inspect the sample and reagents. Remove bubbles or foam before loading tubes and vials onto the instrument. Review the error screen for liquid flow or liquid level errors that are time related and troubleshoot as necessary. Rerun the test. If the error persists, inspect the SYRINGE, DILUTOR VALVE, and TIP TUBING fittings for leaks. Perform the PIPETTE Volume Test to verify metering system integrity.
LTL	Light Too Low	No Result Reported	The light level between the columns is checked with every read; the adjacent light level read was too low. This may be caused when too many red blood cells were pipetted.	There may be debris on the card, or there was not enough sample plasma and red blood cells were aspirated instead of plasma. If there were too many RBCs in the column, they can block light. If the result code is intermittent, there may be debris on the card. Clean the debris from the surface of the cards and rerun the test. Check the sample container and if the plasma has been depleted, rerun the test using a new sample.
LTH	Light Too High	No Result Reported	The light level between the columns is checked with every read; the adjacent light level was too high.	Inspect the card for holes or reflective debris, and rerun the test. If the result code is frequent, the user may need to clean or adjust the IMAGING SYSTEM.
CI	Contrast Interference	No Result Reported	The liquid in the column above the media was dark and the IMAGING SYSTEM could not confidently interpret the reaction. This can be caused by hemolysis, icterus, turbidity or lipemia.	Rerun the test, or manually read the reaction.

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

Result Code	Definition	Column Interpretation	Conditions	Suggested Actions
NC	No Cells	No Result Reported	The IMAGING SYSTEM found that there were no cells or almost no cells in the column.	There may be insufficient reagent or sample volume. Confirm there is reagent and sample available and rerun the test.
TFC	Too Few Cells	No Result Reported	The IMAGING SYSTEM determined that there were not sufficient cells in the column for a valid interpretation.	There may be insufficient reagent or sample volume, or red blood cells may not have been properly suspended. Check the reagent vials and replace them if necessary. Rerun the test.
TMC	Too Many Cells	No Result Reported	The IMAGING SYSTEM determined that there were too many cells in the column for a valid interpretation.	Reagent red blood cells may not have been properly suspended, RBCs may have evaporated, or there was not enough sample plasma and patient RBCs aspirated instead of plasma. If it is suspected that the reagent red blood cells have been compromised due to improper suspension or evaporation discard all vials from that set and replace with a new set. Resuspend the reagents and rerun the test. If the user suspects the sample is the source of the TMC code, make sure there is adequate plasma volume and rerun the test. Recentrifuge the sample if needed.
MF	Mixed Field	No Result Reported	The distribution of the cells within the column indicates that there may be a dual population of cells.	Manually interpret the reaction; follow your laboratory Standard Operating Procedures for dual population reactions.
?	Indeterminate	No Result Reported	The strength of the reaction or the distribution of the cells within the reaction prevented the IMAGING SYSTEM from determining whether the reaction was positive or negative.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures.
FIB	Fibrin	No result reported	The IMAGING SYSTEM saw an agglutinate which may have been caused by fibrin in the sample.	• Manually review the card. • Follow Standard Operating Procedures for the sample for manually reviewing, reporting results and retesting. • Inspect the sample for quality issues. Follow your Standard Operating Procedures for sample processing before testing. • Adjust the centrifugation speed and time to achieve the optimal cell/plasma separation. • If the problem persists, call OCD Customer Technical Support.

ORTHO VISION™ ANALYZER SYSTEM FLAGS AND CODES

Result Code	Definition	Column Interpretation	Conditions	Suggested Actions
BUB	Bubble	If a bubble is found during the preprocessing check the column will be marked as not usable; if a bubble is found during the post processing check the result is not reported.	The IMAGAING SYSTEM detected a bubble that was large enough to effect the reaction.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures
FOC	Focus Error	If the focus targets appear to be incorrect in the preprocessing check the card will be marked as not usable; if the focus targets do not look correct during the post processing check the result is not reported.	The focus targets appear to be incorrect to the IMAGING SYSTEM.	Inspect the focus targets for debris and clean them if necessary.
PE	Position Error	No Result Reported	The IMAGAING SYSTEM has determined that the card is not properly positioned.	If the result code is intermittent, rerun the test.
CVE	Column Volume Error	If the liquid volume is inadequate during the preprocessing check the column will be marked as not usable.	The liquid volume above the media is inadequate.	Evaporation of the column liquid may have occurred or the system rejected the card before it was used and automatically ran the test using another card. Refer to the Card IFU to determine proper disposition of the Card.
CND	Card Not Detected	No Result Reported	The IMAGING SYSTEM has determined that the card is not properly positioned or is missing.	If the result code is intermittent, rerun the test.

Flags

Results flag information identifies results that are above or below the reportable range. If the result has been flagged, the information listed below is shown:

- Accepted/Rejected
- Transferred to LIS
- Instrument simulated
- Result edited by user

In addition, the flags listed below require a manual review of the result:

- Result expired
- Errors from imaging system
- QC expired
- Lot expiration
- Sensor reading temperature dropping out of the notification range
- Sensor reading humidity dropping out of the notification range
- Maintenance expired/failed
- Edited results

Note: The Suggested Actions described in the preceding table reflects ORTHO VISION™ recommendations. The Blood Bank policies supersede any Ortho recommendations given. Follow department policies when applicable.