HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Column Technology using Ortho Clinical Diagnostic Systems		
Applies To:	All Blood Bank Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-207
Approval Date:	January 20, 2025	**Version:**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-207(1)
Review Date:	February 20, 2028	**No. of Pages:**	25

1. PURPOSE:

1.1 All purposes mentioned in (column technology and the gel micro typing system) are applied.

2. DEFINITONS:

2.1 **MTS**: micro typing system. It's a registered mark for Micro Typing Systems®, Inc. a division of Ortho-Clinical Diagnostics, Inc.
2.2 **ID-MTS™** is a trademark of Micro Typing Systems, Inc.
2.3 **ORTHO™ Workstation** is an integrated system of ID-MTS™ Gel Cards, centrifuge and incubator.

3. POLICY:

3.1 A standardised procedure to perform, interpret, and report gel reactions will contribute to uniformity and reproducibility of test results.
3.2 In MCH blood bank, Ortho Clinical Diagnostic (OCD) systems are used as an alternative to ID-system guided by the needs and reagent availability.
3.3 The same principles, reading and grading, and interpretation of ID-system mentioned in "column technology and the gel micro typing system" chapter apply.
3.4 Two systems are available; manual (ortho™ Workstation) and automated (ortho vision® Analyser). The automated system is usually reserved for donor testing.
3.5 Manufacturer's directions should always be followed.

4. PROCEDURE:

4.1 Manual ocd system using ortho™Workstation: ortho™Workstation is an integrated system of ID-MTS™ Gel Cards, centrifuge and incubator.
- 4.1.1 General procedure to be applied to ortho BioVue® Cassettes"
  - 4.1.1.1 Visual control of the ORTHO BioVue® cassettes:
    - 4.1.1.1.1 Do not use reagents beyond their labelled expiration date.
    - 4.1.1.1.2 Do not use cassettes that appear damaged (i.e., break in foil seal or a break, crack or bubble in the column) or exhibit drying (i.e., liquid level is at or below the top of the glass beads) or exhibit discoloration (due to bacterial contamination which can cause false reactions).
  - 4.1.1.2 Sample identification and preparation
  - 4.1.1.3 Cassettes identification and preparation
  - 4.1.1.4 Reagent pipetting
  - 4.1.1.5 Sample pipetting
  - 4.1.1.6 Incubation – Centrifugation
  - 4.1.1.7 Reading
  - 4.1.1.8 Notes: ORTHO BioVue® electronic pipette:
    - 4.1.1.8.1 The pipetter is operated via the six-key keypad and LCD display.
    - 4.1.1.8.2 Five modes or programs (P1, P2, P3, P4, and P5) can be selected.
    - 4.1.1.8.3 The mode function is selected by repeatedly pressing M to locate the desired function in the display and then confirmed by pressing E.

4.1.1.8.4 There are 2 dispense modes;

4.1.1.8.4.1 Multi-dispense mode (P1, P2, P3 and P4): where The pipetter performs repetitive dispenses according to the selected mode (P1, P2, P3 or P4).

4.1.1.8.4.2 Dilute-dispense mode (P5): enables simultaneous dispenses of two different liquids according to the selected mode (P5).

4.1.1.8.5 To select the number of dispenses for a multi-dispense mode, scroll through the display using the ▲ and ▼ keys to the desired number and confirm by pressing E. The speeds are selected using the S ► key and confirmed by pressing E.

4.1.1.8.6 Note that the mode can only be selected when the tip is empty and the ► ARROW is displayed.

4.1.1.8.7 The following parameters can be selected:

4.1.1.8.7.1 Operating mode (symbol in display):

4.1.1.8.7.1.1 multidispense 40 µL (P1)

4.1.1.8.7.1.2 multidispense 10 µL (P2)

4.1.1.8.7.1.3 multidispense 50 µL (P3)

4.1.1.8.7.1.4 multidispense 60 µL (P4)

4.1.1.8.7.1.5 dilute-dispense 190 µL + 10 µL (P5)

4.1.1.8.7.2 Number of dispenses:

4.1.1.8.7.2.1 1 - 6 times with 40 µL

4.1.1.8.7.2.2 1 - 24 times with 10 µL

4.1.1.8.7.2.3 1 - 6 times with 50 µL

4.1.1.8.7.2.4 1 - 6 times with 60 µL

4.1.1.8.7.3 Speed Selection:

4.1.1.8.7.3.1 The aspiration and dispense speeds can be selected from 1 to 5, 1 being the slowest. The default speed is 3.

4.1.1.8.8 Multi-dispense mode (P1, P2, P3 and P4) selection:

4.1.1.8.8.1 Press M to scroll through the operating modes in the display and stop when the desired mode (P1, P2, P3 or P4) is displayed.

4.1.1.8.8.2 Press E to confirm the mode. The dispense volume appears in the right display and the maximum number of dispenses for the dispense volume appears in the left display.

4.1.1.8.8.3 Scroll through the left display using the ▲ and ▼ keys and stop when the desired number of dispenses is displayed.

4.1.1.8.8.4 Press E to confirm. The ► ARROW is displayed to indicate that the pipetter is ready to aspirate the liquid.

4.1.1.8.8.5 Place the tip into the liquid and press the START button to aspirate. The ◄ ARROW is displayed to indicate that the pipetter is ready to dispense.

4.1.1.8.8.6 Press the START button a second time. The display will show the number of dispenses available and the volume. After each dispense, the left display indicates the number of dispenses remaining.

4.1.1.8.8.7 When the last dispense has been performed, an E will appear in the left display to indicate that the excess volume is left in the tip. Press the START button twice to empty the tip. This ensures that an accidental dispense does not occur.

4.1.1.8.8.8 NOTE: The dispense can be interrupted by pressing E. An ARROW and E appear in the display. Pressing the START button will empty the tip.

4.1.1.8.9 Dilute-dispense mode (P5) selection:

4.1.1.8.9.1 Press M to scroll through the operating modes in the display and stop when P5 is displayed.
4.1.1.8.9.2 Press E to confirm the mode.
4.1.1.8.9.3 The first volume and the ► ARROW are displayed. Place the tip into the first liquid and press the START button. The first liquid is aspirated.
4.1.1.8.9.4 The letter A appears in the left display. Remove the tip from the liquid and press the START button to form a small air gap. Wipe the pipette tip.
4.1.1.8.9.5 The second volume and the ► ARROW are displayed. Place the tip into the second liquid and press the START button. The second liquid is aspirated.
4.1.1.8.9.6 The total volume appears in the display to indicate that the Pipetter is ready to dispense both liquids. Press the START button and the tip empties with a blowout.
4.1.1.8.9.7 In mode P5, when the START button is depressed during delivery, the pipetter will stop on the down most position for as long as the button is depressed.

4.1.2 Preparation of blood sample:
- 4.1.2.1 Preparation of 3-5% RBCs Suspensions:
  - 4.1.2.1.1 ORTHO BioVue® electronic pipette – (Program P5)
    - 4.1.2.1.1.1 190 µl NaCl + 10 µl packed red blood cells = 200 µl 3 -5% red blood cells suspension.
  - 4.1.2.1.2 Manual preparation:
    - 4.1.2.1.2.1 Mix 1 ml NaCl + 50 µl packed red blood cells
- 4.1.2.2 Preparation of 0.8% RBCs Suspensions:
  - 4.1.2.2.1 In Saline:
    - 4.1.2.2.1.1 1 ml Saline + 10 µl packed red blood cells
  - 4.1.2.2.2 In 0.8% ORTHO® Red Cell Diluent – for 0.8% Cross-Match:
    - 4.1.2.2.2.1 Mix 1 ml 0.8% ORTHO® Red Cell Diluent + 10 µl packed donor red blood cells
- 4.1.2.3 Maximum storage time at 2 - 8°C for 24 hours.

4.1.3 ABO/D typing:
- 4.1.3.1 Cassettes:
  - 4.1.3.1.1 ORTHO BioVue® ABO-Rh (A, B, AB, D, CDE, Control) *or*
  - 4.1.3.1.2 ORTHO BioVue® ABODD (A, B, AB, D, D, Control) *or*
  - 4.1.3.1.3 ORTHO BioVue® ABDD/K (A, B, D, D, Kell, Control) *or*
  - 4.1.3.1.4 ORTHO BioVue® ABD Confirmation (A, B, D, A, B, D)
- 4.1.3.2 Sample:
  - 4.1.3.2.1 3-5% patient red blood cells suspensions in saline (4.1.2.1) *or*
  - 4.1.3.2.2 0.8% patient red blood cells suspensions in saline (4.1.2.2)
- 4.1.3.3 3-5% Procedure:
  - 4.1.3.3.1 Identify the cassette
  - 4.1.3.3.2 Add 10 µl 3-5% patient red blood cells suspensions - P2
  - 4.1.3.3.3 5 minutes centrifugation
  - 4.1.3.3.4 Reading (both sides)
- 4.1.3.4 0.8% Procedure:
  - 4.1.3.4.1 Identify the cassette
  - 4.1.3.4.2 Add 50 µl 0.8% patient red blood cells suspensions - P3
  - 4.1.3.4.3 5 minutes centrifugation
  - 4.1.3.4.4 Reading (both sides)

4.1.4 ABO Reverse Typing:
- 4.1.4.1 Cassettes:
  - 4.1.4.1.1 ORTHO BioVue® Reverse Diluent (6 x Reverse)
- 4.1.4.2 Reagents:
  - 4.1.4.2.1 Affirmagen® 4 (A1, A2, B & O cells) or

4.1.4.2.2 0.8% Affirmagen® 4 (A1, A2, B & O cells) or
4.1.4.2.3 Affirmagen® 2 (A1 & B cells) or
4.1.4.2.4 0.8% Affirmagen® 2 (A1 & B cells) or

4.1.4.3 Sample:
4.1.4.3.1 Patient Serum/Plasma.

4.1.4.4 3-5% Procedure:
4.1.4.4.1 Identify the cassette
4.1.4.4.2 Add 10 µl Affirmagen® 2 (A1, A2, B & O cells) - P2
4.1.4.4.3 Add 40 µl patient serum/plasma - P1
4.1.4.4.4 5 minutes centrifugation
4.1.4.4.5 Reading (both sides)

4.1.4.5 0.8% Procedure:
4.1.4.5.1 Identify the cassette
4.1.4.5.2 Add 50 µl 0.8% Affirmagen® 2 (A1, A2, B & O cells) - P3
4.1.4.5.3 Add 40 µl patient serum/plasma - P1
4.1.4.5.4 5 minutes centrifugation
4.1.4.5.5 Reading (both sides)

4.1.5 ABO/D Typing & ABO Reverse Typing:

4.1.5.1 Cassettes:
4.1.5.1.1 ORTHO BioVue® ABO-Rh D Combo (A, B, D, Control, Reverse, Reverse)

4.1.5.2 Reagents:
4.1.5.2.1 Affirmagen® 2 (A1 & B cells) or
4.1.5.2.2 0.8% Affirmagen® 2 (A1 & B cells) or

4.1.5.3 Sample:
4.1.5.3.1 3-5% patient or donor red blood cells suspensions (4.1.2.1)
4.1.5.3.2 0.8% patient or donor red blood cells suspensions (4.1.2.2)
4.1.5.3.3 Patient Serum/Plasma

4.1.5.4 3-5% Procedure:
4.1.5.4.1 Identify the cassette
4.1.5.4.2 Add 10 µl Affirmagen® 2 (A1 & B cells) in the reverse columns - P2
4.1.5.4.3 Add 40 µl patient serum/plasma in the reverse columns - P1
4.1.5.4.4 Add 10 µl 3-5% patient red blood cells suspensions in the A, B, D & Control columns - P2
4.1.5.4.5 5 minutes centrifugation
4.1.5.4.6 Reading (both sides)

4.1.5.5 0.8% Procedure:
4.1.5.5.1 Identify the cassette
4.1.5.5.2 Add 50 µl 0.8% Affirmagen® 2 (A1 & B cells) in the reverse columns - P3
4.1.5.5.3 Add 40 µl patient serum/plasma in the reverse columns - P1
4.1.5.5.4 Add 50 µl 0.8% patient red blood cells suspensions in the A, B, D & Control columns - P3
4.1.5.5.5 5 minutes centrifugation
4.1.5.5.6 Reading (both sides)

4.1.6 ABO/D + Direct Coombs – Newborn:

4.1.6.1 Cassettes:
4.1.6.1.1 ORTHO BioVue® Newborn (A, B, AB, D, Control, AHG Anti-IgG)

4.1.6.2 Sample:
4.1.6.2.1 3-5% patient red blood cells suspensions in saline (4.1.2.1)
4.1.6.2.2 0.8% patient red blood cells suspensions in saline (4.1.2.2)

4.1.6.3 3-5% Procedure:
4.1.6.3.1 Identify the cassette
4.1.6.3.2 Add 10 µl 3-5% patient red blood cells suspensions - P2
4.1.6.3.3 5 minutes centrifugation
4.1.6.3.4 Reading (both sides)

4.1.6.4 0.8% Procedure:
4.1.6.4.1 Identify the cassette

4.1.6.4.2 Add 50 µl 0.8% patient red blood cells suspensions - P3
4.1.6.4.3 5 minutes centrifugation
4.1.6.4.4 Reading (both sides)

4.1.7 Rh/K Phenotyping:
4.1.7.1 Cassettes:
4.1.7.1.1 ORTHO BioVue® Rh/K (C, E, c, e, K, Control)
4.1.7.1.2 ORTHO BioVue® Rh-hr (D, C, E, c, e, Control)
4.1.7.1.3 ORTHO BioVue® Kell (6 x K)
4.1.7.1.4 ORTHO BioVue® Kell/Control (K, Control, K, Control, K, Control)
4.1.7.2 Sample:
4.1.7.2.1 3-5% patient red blood cells suspensions in saline (4.1.2.1)
4.1.7.2.2 0.8% patient red blood cells suspensions in saline (4.1.2.2)
4.1.7.3 3-5% Procedure:
4.1.7.3.1 Identify the cassette
4.1.7.3.2 Add 10 µl 3-5% patient red blood cells suspensions - P2
4.1.7.3.3 5 minutes centrifugation
4.1.7.3.4 Reading (both sides)
4.1.7.4 0.8% Procedure:
4.1.7.4.1 Identify the cassette
4.1.7.4.2 Add 50 µl 0.8% patient red blood cells suspensions - P3
4.1.7.4.3 5 minutes centrifugation
4.1.7.4.4 Reading (both sides)

4.1.8 Direct Coombs:
4.1.8.1 Cassettes:
4.1.8.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or*
4.1.8.1.2 ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.8.2 Sample:
4.1.8.2.1 3-5% patient red blood cells suspensions in saline (4.1.2.1)
4.1.8.3 Procedure:
4.1.8.3.1 Identify the cassette
4.1.8.3.2 Add 10 µl 3-5% patient red blood cells suspensions - P2
4.1.8.3.3 5 minutes centrifugation
4.1.8.3.4 Reading (both sides)

4.1.9 Direct Coombs Specific:
4.1.9.1 Cassettes:
4.1.9.1.1 ORTHO BioVue® DAT/IDAT (AHG Anti-IgG, Anti-C3b & -C3d, Control)
4.1.9.2 Sample:
4.1.9.2.1 3-5% patient red blood cells suspensions in saline (4.1.2.1)
4.1.9.3 Procedure:
4.1.9.3.1 Identify the cassette
4.1.9.3.2 Add 10 µl 3-5% patient red blood cells suspensions - P2
4.1.9.3.3 5 minutes centrifugation
4.1.9.3.4 Reading (both sides)

4.1.10 3-5% Antibody Screening - Indirect Coombs Technique:
4.1.10.1 Cassettes:
4.1.10.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or* ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.10.2 Reagents:
4.1.10.2.1 Selectogen® (2 cells) *or* Surgiscreen® (3 cells) *and* Ortho® BLISS
4.1.10.3 Sample:
4.1.10.3.1 Patient Serum/Plasma
4.1.10.4 Procedure:
4.1.10.4.1 Identify the cassette
4.1.10.4.2 Add 50 µl Ortho® BLISS - P3
4.1.10.4.3 Add 10 µl 3-5% Test Red Blood Cells - P2
4.1.10.4.4 Add 40 µl patient serum/plasma - P1

4.1.10.4.5 10 – 15 minutes incubation (Max. 30 minutes)
4.1.10.4.6 5 minutes centrifugation
4.1.10.4.7 Reading (both sides)

4.1.11 0.8% Antibody Screening - Indirect Coombs Technique:
4.1.11.1 Cassettes:
4.1.11.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or* ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.11.2 Reagents:
4.1.11.2.1 0.8% Selectogen® (2 cells) *or* 0.8% Surgiscreen® (3 cells)
4.1.11.3 Sample:
4.1.11.3.1 Patient Serum/Plasma
4.1.11.4 Procedure:
4.1.11.4.1 Identify the cassette
4.1.11.4.2 Add 50 µl 0.8% Test Red Blood Cells - P3
4.1.11.4.3 Add 40 µl patient serum/plasma - P1
4.1.11.4.4 10 – 15 minutes incubation (Max. 30 minutes)
4.1.11.4.5 5 minutes centrifugation
4.1.11.4.6 Reading (both sides)

4.1.12 3-5% Antibody Screening - IAT & Enzyme Technique:
4.1.12.1 Cassettes:
4.1.12.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific/Neutral
4.1.12.2 Reagents:
4.1.12.2.1 ORTHO BioVue® Screen Ficin (3 untreated & 3 ficin-treated cells) *and* Ortho® BLISS
4.1.12.3 Sample:
4.1.12.3.1 Patient Serum/Plasma
4.1.12.4 Procedure:
4.1.12.4.1 Identify the cassette
4.1.12.4.2 Add 50 µl Ortho® BLISS in the 3 Polyspecific Columns - P3
4.1.12.4.3 Add 10 µl 3-5% untreated Test Red Blood Cells in the 3 Polyspecific Columns - P2
4.1.12.4.4 Add 10 µl 3-5% ficin-treated Test Red Blood Cells in the 3 neutral Columns - P2
4.1.12.4.5 Add 40 µl patient serum/plasma in the 6 columns - P1
4.1.12.4.6 10 – 15 minutes incubation (Max. 30 minutes)
4.1.12.4.7 5 minutes centrifugation
4.1.12.4.8 Reading (both sides)

4.1.13 0.8% Antibody Screening - IAT & Enzyme Technique:
4.1.13.1 Cassettes:
4.1.13.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific/Neutral
4.1.13.2 Reagents:
4.1.13.2.1 0.8% ORTHO BioVue® Screen Ficin (3 untreated & 3 ficin-treated cells)

4.1.13.3 Sample:
4.1.13.3.1 Patient Serum/Plasma
4.1.13.4 Procedure:
4.1.13.4.1 Identify the cassette
4.1.13.4.2 Add 50 µl 0.8% untreated Test Red Blood Cells in the 3 Polyspecific Columns - P3
4.1.13.4.3 Add 50 µl 0.8% ficin-treated Test Red Blood Cells in the 3 neutral Columns - P3
4.1.13.4.4 Add 40 µl patient serum/plasma in the 6 columns - P1
4.1.13.4.5 10 – 15 minutes incubation (Max. 30 minutes)
4.1.13.4.6 5 minutes centrifugation
4.1.13.4.7 Reading (both sides)

4.1.14 3-5% Cross-Match - Indirect Coombs Technique:

4.1.14.1 Cassettes:
4.1.14.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or* ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.14.2 Reagents:
4.1.14.2.1 Ortho® BLISS
4.1.14.3 Sample:
4.1.14.3.1 Patient Serum/Plasma
4.1.14.3.2 3-5% donor red blood cells suspensions in Saline (4.1.2.1)
4.1.14.4 Procedure:
4.1.14.4.1 Identify the cassette
4.1.14.4.2 Add 50 µl Ortho® BLISS in the 3 Polyspecific Columns - P3
4.1.14.4.3 Add 10 µl 3-5% donor red blood cells - P2
4.1.14.4.4 Add 40 µl patient serum/plasma - P1
4.1.14.4.5 10 – 15 minutes incubation (Max. 30 minutes)
4.1.14.4.6 5 minutes centrifugation
4.1.14.4.7 Reading (both sides)

4.1.15 0.8% Cross-Match - Indirect Coombs Technique:
4.1.15.1 Cassettes:
4.1.15.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or* ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.15.2 Reagents:
4.1.15.2.1 0.8% Ortho® Red Cell Diluent
4.1.15.3 Sample:
4.1.15.3.1 Patient Serum/Plasma
4.1.15.3.2 0.8% donor red blood cells suspensions in 0.8% Ortho® Red Cell Diluent (4.1.2.2)
4.1.15.4 Procedure:
4.1.15.4.1 Identify the cassette
4.1.15.4.2 Add 50 µl 0.8% donor red blood cells - P3
4.1.15.4.3 Add 40 µl patient serum/plasma - P1
4.1.15.4.4 10 – 15 minutes incubation (Max. 30 minutes)
4.1.15.4.5 5 minutes centrifugation
4.1.15.4.6 Reading (both sides)

4.1.16 3-5% Cross-Match - Enzyme Technique:
4.1.16.1 Cassettes:
4.1.16.1.1 ORTHO BioVue® Neutral
4.1.16.2 Reagents:
4.1.16.2.1 Enzyme Solution
4.1.16.3 Sample:
4.1.16.3.1 Patient Serum/Plasma
4.1.16.3.2 3-5% donor red blood cells suspensions in Saline (4.1.2.1)
4.1.16.4 Procedure:
4.1.16.4.1 Identify the cassette
4.1.16.4.2 Add 40 µl Enzyme - P1
4.1.16.4.3 Add 10 µl 3-5% donor red blood cells - P2
4.1.16.4.4 Add 40 µl patient serum/plasma - P1
4.1.16.4.5 10 – 15 minutes incubation
4.1.16.4.6 5 minutes centrifugation
4.1.16.4.7 Reading (both sides)

4.1.17 3-5% Antibody Identification - Indirect Coombs Technique:
4.1.17.1 Cassettes:
4.1.17.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or* ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.17.2 Reagents:
4.1.17.2.1 Resolve® Panel A (11 cells), Resolve® Panel B (11 cells) *or* Resolve® Panel (R) C (11 cells untreated) *and* Ortho® BLISS

4.1.17.3 Sample:
4.1.17.3.1 Patient Serum/Plasma
4.1.17.4 Procedure:
4.1.17.4.1 Identify the cassette
4.1.17.4.2 Add 50 µl Ortho® BLISS - P3
4.1.17.4.3 Add 10 µl 3-5% Test Red Blood Cells - P2
4.1.17.4.4 Add 40 µl patient serum/plasma - P1
4.1.17.4.5 10 – 15 minutes incubation (Max. 30 minutes)
4.1.17.4.6 5 minutes centrifugation
4.1.17.4.7 Reading (both sides)

4.1.18 0.8% Antibody Identification - Indirect Coombs Technique:
4.1.18.1 Cassettes:
4.1.18.1.1 ORTHO BioVue® Anti-Human Globulin Polyspecific *or* ORTHO BioVue® Anti-Human Globulin Anti-IgG
4.1.18.2 Reagents:
4.1.18.2.1 0.8% Resolve® Panel A (11 cells), 0.8% Resolve® Panel B (11 cells) *or*0.8% Resolve® Panel (R) C (11 cells untreated)
4.1.18.3 Sample:
4.1.18.3.1 Patient Serum/Plasma
4.1.18.4 Procedure:
4.1.18.4.1 Identify the cassette
4.1.18.4.2 Add 50 µl 0.8% Test Red Blood Cells - P3
4.1.18.4.3 Add 40 µl patient serum/plasma - P1
4.1.18.4.4 10 – 15 minutes incubation (Max. 30 minutes)
4.1.18.4.5 5 minutes centrifugation
4.1.18.4.6 Reading (both sides)

4.1.19 3-5% Antibody Identification - Enzyme Technique:
4.1.19.1 Cassettes:
4.1.19.1.1 ORTHO BioVue® Neutral
4.1.19.2 Reagents:
4.1.19.2.1 Resolve® Panel C (the 11 ficin-treated cells)
4.1.19.3 Sample:
4.1.19.3.1 Patient Serum/Plasma
4.1.19.4 Procedure:
4.1.19.4.1 Identify the cassette
4.1.19.4.2 Add 10 µl ficin-treated Test Red Blood Cells - P2
4.1.19.4.3 Add 40 µl patient serum/plasma - P1
4.1.19.4.4 10 – 15 minutes incubation (Max. 30 minutes)
4.1.19.4.5 5 minutes centrifugation
4.1.19.4.6 Reading (both sides)

4.1.20 0.8% Antibody Identification - Enzyme Technique:
4.1.20.1 Cassettes:
4.1.20.1.1 ORTHO BioVue® Neutral
4.1.20.2 Reagents:
4.1.20.2.1 0.8% Resolve® Panel C (the 11 ficin-treated cells)
4.1.20.3 Sample:
4.1.20.3.1 Patient Serum/Plasma
4.1.20.4 Procedure:
4.1.20.4.1 Identify the cassette
4.1.20.4.2 Add 50 µl ficin-treated Test Red Blood Cells - P3
4.1.20.4.3 Add 40 µl patient serum/plasma - P1
4.1.20.4.4 10 – 15 minutes incubation (Max. 30 minutes)
4.1.20.4.5 5 minutes centrifugation
4.1.20.4.6 Reading (both sides)

4.1.21 Extended Phenotyping – Anti-Fya, Anti- Fyb, Anti-S, Anti-s, Anti-D (IAT):
4.1.21.1 Cassettes:

4.1.21.1.1 ORTHO BioVue® Anti-Human Globulin Anti-IgG

4.1.21.2 Reagents:

4.1.21.2.1 ORTHO™ Sera Anti-Fya (Anti-FY1)

4.1.21.2.2 ORTHO™ Sera Anti-Fyb (Anti-FY2)

4.1.21.2.3 ORTHO™ Sera Anti-S (Anti-MNS3)

4.1.21.2.4 ORTHO™ Sera Anti-s (Anti-MNS4)

4.1.21.2.5 ORTHO™ Sera Anti-D (IAT) (Anti-RH1)

4.1.21.3 Sample:

4.1.21.3.1 3-5% patient red blood cells suspensions in saline (4.1.2.1) *or*

4.1.21.3.2 0.8% patient red blood cells suspensions in saline (4.1.2.2)

4.1.21.4 3-5% Procedure:

4.1.21.4.1 Identify the cassette

4.1.21.4.2 Add 40 µl ORTHO Sera - P1

4.1.21.4.3 Add 10 µl 3-5% patient red blood cells suspensions - P2

4.1.21.4.4 15 minutes incubation

4.1.21.4.5 5 minutes centrifugation

4.1.21.4.6 Reading (both sides)

4.1.21.5 0.8% Procedure:

4.1.21.5.1 Identify the cassette

4.1.21.5.2 Add 40 µl ORTHO Sera - P1

4.1.21.5.3 Add 50 µl 0.8% patient red blood cells suspensions - P3

4.1.21.5.4 15 minutes incubation

4.1.21.5.5 5 minutes centrifugation

4.1.21.5.6 Reading (both sides)

4.1.22 Extended Phenotyping – Anti-Jka, Anti-Jkb, Anti-K, Anti-D (DVI), Anti-P1, Anti- Lea, Anti-Leb:

4.1.22.1 Cassettes:

4.1.22.1.1 ORTHO BioVue® Reverse Diluent (6 x Reverse)

4.1.22.2 Reagents:

4.1.22.2.1 ORTHO™ Sera Anti-Jka (Anti-JK1)

4.1.22.2.2 ORTHO™ Sera Anti-Jkb (Anti-JK2)

4.1.22.2.3 ORTHO™ Sera Anti-K (Anti-KEL1)

4.1.22.2.4 ORTHO™ Sera Anti-D (DVI) (Anti-RH1)

4.1.22.2.5 ORTHO™ Sera Anti-P1 (Anti-P1PK1)

4.1.22.2.6 ORTHO™ Sera Anti-Lea (Anti-LE1)

4.1.22.2.7 ORTHO™ Sera Anti-Leb (Anti-LE2)

4.1.22.3 Sample:

4.1.22.3.1 3-5% patient red blood cells suspensions in saline (4.1.2.1)

4.1.22.3.2 0.8% patient red blood cells suspensions in saline (4.1.2.2)

4.1.22.4 3-5% Procedure:

4.1.22.4.1 Identify the cassette

4.1.22.4.2 Add 40 µl ORTHO Sera - P1

4.1.22.4.3 Add 10 µl 3-5% patient red blood cells suspensions - P2

4.1.22.4.4 5 minutes centrifugation

4.1.22.4.5 Reading (both sides)

4.1.22.5 0.8% Procedure:

4.1.22.5.1 Identify the cassette

4.1.22.5.2 Add 40 µl ORTHO Sera - P1

4.1.22.5.3 Add 50 µl 0.8% patient red blood cells suspensions - P3

4.1.22.5.4 5 minutes centrifugation

4.1.22.5.5 Reading (both sides)

4.1.23 Extended Phenotyping – Anti-M, Anti-N:

4.1.23.1 Cassettes:

4.1.23.1.1 ORTHO BioVue® Neutral

4.1.23.2 Reagents:

4.1.23.2.1 ORTHO™ Sera Anti-M (Anti-MNS1)

4.1.23.2.2 ORTHO™ Sera Anti-N (Anti-MNS2)

4.1.23.3 Sample:
- 4.1.22.3.1 3-5% patient red blood cells suspensions in saline (4.1.2.1) *or*
- 4.1.22.3.2 0.8% patient red blood cells suspensions in saline (4.1.2.2)

4.1.23.4 3-5% Procedure:
- 4.1.23.4.1 Identify the cassette
- 4.1.23.4.2 Add 40 µl ORTHO Sera - P1
- 4.1.23.4.3 Add 10 µl 3-5% patient red blood cells suspensions - P2
- 4.1.23.4.4 5 minutes centrifugation
- 4.1.23.4.5 Reading (both sides)

4.1.23.5 0.8% Procedure:
- 4.1.23.5.1 Identify the cassette
- 4.1.23.5.2 Add 40 µl ORTHO Sera - P1
- 4.1.23.5.3 Add 50 µl 0.8% patient red blood cells suspensions - P3
- 4.1.23.5.4 5 minutes centrifugation
- 4.1.23.5.5 Reading (both sides)

4.1.24 Ortho biovue® results interpretation

4.1.24.1 Agglutination grading chart:

4.1.24.1.1

Grade	Description
4+	Agglutinated cells form a band at the top of the bead column.
3+	Most agglutinated cells remain in the upper half of the bead column.
2+	Agglutinated cells observed throughout the length of the bead column. A small button of cells may also be visible at the bottom of the bead column.
1+	Most agglutinated cells remain in the lower half of the bead column. A button of cells will also be visible at the bottom of the bead column.
Negative	All cells pass through the beads and form a button at the bottom of the bead column.

4.1.24.2 Difficulties solving/troubleshooting:

4.1.24.2.1 Low liquid level after test is finished:

4.1.24.2.1.1 Possible Effect:
- 4.1.24.2.1.1.1 False negative result

4.1.24.2.1.2 Cause:
- 4.1.24.2.1.2.1 No sample has been added

4.1.24.2.1.3 Solution(s):
- 4.1.24.2.1.3.1 Test has to be repeated
- 4.1.24.2.1.3.2 Check that reagent(s) and sample are added

4.1.24.2.2 Top line:

4.1.24.2.2.1 Possible Effect:
- 4.1.24.2.2.1.1 False positive interpretation
- 4.1.24.2.2.1.2 Reaction like mixed field

4.1.24.2.2.2 Cause:
- 4.1.24.2.2.2.1 Fibrin or particulates in serum or plasma
- 4.1.24.2.2.2.2 Incompletely washed RBC of donor (XM)
- 4.1.24.2.2.2.3 Red blood cells that stick to the sides of the reaction chamber and fall down later and stay above the glass beads

4.1.24.2.2.3 Solution(s):
- 4.1.24.2.2.3.1 Elimination of fibrin or particulates with centrifugation of the sample
- 4.1.24.2.2.3.2 Wash red blood cells one time with saline

4.1.24.2.2.3.3 Result should be read within 1 hour after the centrifugation
4.1.24.2.2.3.4 Check patient history

4.1.24.2.3 Hemolysis:
4.1.24.2.3.1 Possible Effect:
4.1.24.2.3.1.1 Liquid above glass beads is red coloured
4.1.24.2.3.1.2 No agglutination
4.1.24.2.3.1.3 Cells haze above glass beads column
4.1.24.2.3.2 Cause:
4.1.24.2.3.2.1 Bad quality of the erythrocytes
4.1.24.2.3.2.2 Hemolytic serum or plasma has been used for the test
4.1.24.2.3.2.3 Serum or plasma contains hemolytic antibodies
4.1.24.2.3.3 Solution(s):
4.1.24.2.3.3.1 Storage and expiration dates of RBC should be checked. Test should be repeated with a new sample.
4.1.24.2.3.3.2 Check if sample is already hemolytic
4.1.24.2.3.3.3 Antibody identification should be done
4.1.24.2.3.3.4 Test could be repeated with washed cells

4.1.24.2.4 Mixed field:
4.1.24.2.4.1 Possible Effect:
4.1.24.2.4.1.1 Mixed field reaction = strong positive agglutination above the beads and cell button in the bottom of the column
4.1.24.2.4.2 Cause:
4.1.24.2.4.2.1 Occurs often after transfusion, transplantation, etc.
4.1.24.2.4.2.2 Could occur when using pooled test cells
4.1.24.2.4.3 Solution(s):
4.1.24.2.4.3.1 Check patient history and eventual transfusion
4.1.24.2.4.3.2 Antibody identification

4.1.24.2.5 "Old" RBCs:
4.1.24.2.5.1 Possible Effect:
4.1.24.2.5.1.1 False positive results
4.1.24.2.5.1.2 "Disrupted" reaction
4.1.24.2.5.1.3 Not indeterminate reaction haze
4.1.24.2.5.2 Cause:
4.1.24.2.5.2.1 Some old, clotted samples and samples with anticoagulants could absorb, after long storage, low concentration of complement and IgG. The BioVue system is a very sensitive system and could detect the Ig. Disrupted reactions are often a case of complement binding effect. Such reactions are difficult to reproduce.
4.1.24.2.5.2.2 The membranes of erythrocytes changed during the storage, particularly when donor blood and RBCs don't contain additives. Those red blood cells cannot pass the glass beads filter and the

reaction is like a pink haze above the beads.

4.1.24.2.5.3 Solution(s):
- 4.1.24.2.5.3.1 Repeat the test(s) with fresh erythrocytes
- 4.1.24.2.5.3.2 Washing and suspension in saline of the erythrocytes

4.1.24.2.6 Bubble in the glass beads column:
- 4.1.24.2.6.1 Possible Effect:
  - 4.1.24.2.6.1.1 False positive results
- 4.1.24.2.6.2 Cause:
  - 4.1.24.2.6.2.1 Transport and/or storage
- 4.1.24.2.6.3 Solution(s):
  - 4.1.24.2.6.3.1 If RBCs "hangs up" on the bubble, the test should be repeated
  - 4.1.24.2.6.3.2 Cassettes with breaks or bubbles in the glass beads column should not be used

4.1.24.2.7 Before testing, liquid level above glass beads is low (<1 mm):
- 4.1.24.2.7.1 Possible Effect:
  - 4.1.24.2.7.1.1 False positive results
  - 4.1.24.2.7.1.2 "J" cell button
- 4.1.24.2.7.2 Cause:
  - 4.1.24.2.7.2.1 Expired cassette
  - 4.1.24.2.7.2.2 Dried/drying column
- 4.1.24.2.7.3 Solution(s):
  - 4.1.24.2.7.3.1 Test has to be repeated with a non-expired cassette
  - 4.1.24.2.7.3.2 Cassettes should not be stored near a heat source. Optimal storage temperature: 2 - 25°C. Do not store the cassettes in a self-defrosting refrigerator/freezer.

4.1.24.2.8 Cold antibodies:

- 4.1.24.2.8.1 Possible Effect:
  - 4.1.24.2.8.1.1 All tests and auto control are positive
- 4.1.24.2.8.2 Cause:
  - 4.1.24.2.8.2.1 Because of the principle of non-washing AHG test and presence of macromolecular potentiators in the column, warm and cold antibodies with lower affinity could react
- 4.1.24.2.8.3 Solution(s):
  - 4.1.24.2.8.3.1 Test(s) should be repeated, Serum/Plasma and RBC should be warmed up to 37°C, incubation time = 30 minutes

4.1.24.2.9 Centrifugation not horizontal:
- 4.1.24.2.9.1 Possible Effect:
  - 4.1.24.2.9.1.1 All columns showed disrupted cell buttons
- 4.1.24.2.9.2 Cause:
  - 4.1.24.2.9.2.1 Cassette carrier is blocked
  - 4.1.24.2.9.2.2 Under/over rotation of cassettes in th centrifuge
- 4.1.24.2.9.3 Solution(s):
  - 4.1.24.2.9.3.1 Cassette carrier should be checked, shou move free and in to the right

4.1.24.2.9.3.2 Balance of cassettes should be checke before starting centrifugation

4.1.24.2.9.3.3 Centrifuge should be installed on a horizont support

4.1.24.2.10 Weak antibodies:

4.1.24.2.10.1 Possible Effect:

4.1.24.2.10.1.1 Nonspecific reactions

4.1.24.2.10.1.2 "J" cell button

4.1.24.2.10.2 Cause:

4.1.24.2.10.2.1 Antibodies with lower titer and/or low affinity in Serum/Plasma

4.1.24.2.10.3 Solution(s):

4.1.24.2.10.3.1 Increase the incubation time to 30 minutes

4.1.24.2.10.3.2 Antibody should be identified

4.1.24.2.10.3.3 If needed, use of enzyme treatment of RBC

4.1.24.2.11 Wrong centrifugation speed:

4.1.24.2.11.1 Possible Effect:

4.1.24.2.11.1.1 False positive results

4.1.24.2.11.1.2 Reactions not clear

4.1.24.2.11.1.3 False negative results

4.1.24.2.11.2 Cause:

4.1.24.2.11.2.1 Centrifugation speed too low: The non-agglutinated erythrocytes stay in the glass beads column (reaction like a weak positive or indeterminate reaction)

4.1.24.2.11.2.2 Centrifugation speed too high: Weak agglutinated cells are pressed to the bottom of the column and give a negative reaction

4.1.24.2.11.3 Solution(s):

4.1.24.2.11.3.1 Centrifugation speed has to be checked regularly

4.1.24.2.11.3.2 Centrifuge outside of the tolerance limits should not be used

4.2. Automated OCD system using ORTHO VISION® Analyzer:

4.2.1 Principle:

4.2.1.1 ORTHO VISION® Analyzer is an automated analyzing system capable of pipetting, incubation, centrifugation, reading and interpretation for ID-Card. It automates the full range of immunohematology testing including blood grouping serology, antibody screening, antigen typing, and other immunohematology tests. In the ID-Gel Test the agglutination does not occur in a liquid phase, but in a gel contained in a special micro tube. The red cells and serum are dispensed in the upper part of this tube. The micro tube is incubated as appropriate and then centrifuged. Formation of red cells pellet in the bottom of the tube is a negative reaction whereas red cells trapped in the gel is a positive reaction. Depending on the strength of the reaction, different patterns may be seen.

4.2.2 The following tests can be done:

4.2.2.1 ABO/RH/Reverse

4.2.2.2 ABO/RH

4.2.2.3 RH/K Phenotype

4.2.2.4 Extended Antigen Typing

4.2.2.5 Donor Confirmation

4.2.2.6 Antibody Screen

4.2.2.7 Antibody Identification
4.2.2.8 Selected Cell Panel
4.2.2.9 Serial Dilutions for Titration Studies
4.2.2.10 DAT
4.2.2.11 Crossmatch (Major)
4.2.2.12 Crossmatch (Minor)
4.2.2.13 Note: the desired tests are grouped within "Assigned Profiles". Each profile may contain one or more test.

4.2.3 Specimen:
4.2.3.1 Packed cells, whole blood and plasma are all acceptable by the machine depending on the tests to be performed.

4.2.4 Reagents, Supplies and Equipment:
4.2.4.1 ORTHO VISION® Analyzer.
4.2.4.2 Ortho® BLISS diluent according to the test required.
4.2.4.3 Enzyme Solution according to the test required.
4.2.4.4 0.8% Ortho® Red Cell Diluent according to the test required.
4.2.4.5 ORTHO BioVue® cassettes according to the test required.
4.2.4.6 ORTHO™ Sera according to the test required.
4.2.4.7 Affirmagen® according to the test required.
4.2.4.8 Surgiscreen® according to the test required.
4.2.4.9 Resolve® Panel according to the test required.
4.2.4.10 0.9% Saline.
4.2.4.11 Distilled water.

4.2.5 Procedure:
4.2.5.1 System start up (system powered off):
4.2.5.1.1 Fill the drawer with required cassettes.
4.2.5.1.2 Load the barcoded dilution trays.
4.2.5.1.3 Ensure that the cassettes waste tray as well as the visual review tray is empty.
4.2.5.1.4 Verify that all doors are closed.
4.2.5.1.5 Note: Samples and agitated reagents should not be on the LOAD STATIONS at start up. Any samples found on board, at the system start up, will be marked as expired. Any liquid reagents in the agitated supply, at start up, will be marked as requiring agitation.

4.2.5.2 System start up and user identification:
4.2.5.2.1 Power on the ORTHO VISION™ Analyzer with the power switch located on the right side of the analyzer.
4.2.5.2.2 Once powered on, the system completes a series of initialization processes.
4.2.5.2.3 The "system Startup" is completed when the "Dashboard" is displayed and you can login.
4.2.5.2.3.1 The Home screen is the first screen that displays once the system is ready.
4.2.5.2.3.2 Log in by touching anywhere on the Home screen to display the User Login screen. Enter your user name and password in the corresponding fields then press Enter.
4.2.5.2.3.3 The Home screen is displayed with the current logged in user.
4.2.5.2.4 The Home screen provides an overview of system processes with the Dashboard, which displays current status information for Resources, Samples, Results, and STAT samples.

4.2.5.3 Resources:
5.2.5.3.1 Loading Resources :
5.2.5.3.1.1 Touch the “Resources” button to access the resources screen
5.2.5.3.1.2 Select the “Resources” menu
5.2.5.3.1.3 Select the “Reagents” button along the side of the Resources screen

5.2.5.3.1.4 Select a Reagent Rack position from the diagram view on the screen
5.2.5.3.1.5 Touch the "Load/Unload" action button.
5.2.5.3.1.6 Place the Reagent rack on the system.
5.2.5.3.1.7 Select the next Reagent Rack position and place the next rack you want to load
5.2.5.3.1.8 Close the door when load/unload is completed
5.2.5.3.1.9 Notes:
5.2.5.3.1.9.1 Follow the manufacturer's instructions regarding time periods where Ortho Reagent Red Blood Cells can be kept on the system
5.2.5.3.1.9.2 Reagent Red Blood Cells must be at room temperature when they are loaded on the system.

5.2.5.3.2 Liquids & Waste :
5.2.5.3.2.1 To refill saline (white container) and deionized water (blue container):
5.2.5.3.2.1.1 Touch the "Resources" button to access the resources screen
5.2.5.3.2.1.2 Select the "Resources" menu
5.2.5.3.2.1.3 Select the "Liquids" button
5.2.5.3.2.1.4 Touch the "Refill" action button.
5.2.5.3.2.1.5 Open the liquid access door
5.2.5.3.2.1.6 Remove the bottles from the system
5.2.5.3.2.1.7 Wait at least 8 seconds
5.2.5.3.2.1.8 Replace the bottles
5.2.5.3.2.1.9 Note: Every time the saline and deionized water containers are refilled, the liquid waste bottle must be emptied.
5.2.5.3.2.2 To empty the liquid waste bottle:
5.2.5.3.2.2.1 Touch the "Resources" button to access the resources screen
5.2.5.3.2.2.2 Select the "Resources" menu
5.2.5.3.2.2.3 Select the "Waste" button
5.2.5.3.2.2.4 Touch the "Empty Liquid" action button.
5.2.5.3.2.2.5 Open the LIQUID ACCESS DOOR
5.2.5.3.2.2.6 Remove the LIQUID WASTE Bottle and empty it
5.2.5.3.2.2.7 Wait at least 8 seconds
5.2.5.3.2.2.8 Replace the bottle
5.2.5.3.2.2.9 Note: Every time the liquid waste bottle is emptied, the saline and deionized water containers must be refilled.
5.2.5.3.2.3 To empty Cassettes Waste:
5.2.5.3.2.3.1 Touch the "Resources" button to access the resources screen
5.2.5.3.2.3.2 Select the "Resources" menu
5.2.5.3.2.3.3 Select the "Waste" button
5.2.5.3.2.3.4 Touch the "Empty Cassette" action button.
5.2.5.3.2.3.5 Open the Waste drawer
5.2.5.3.2.3.6 Empty the Waste Drawer
5.2.5.3.2.3.7 The confirmation dialogue asks you to confirm that the Waste Drawer has been emptied. Select "Yes" to confirm.
5.2.5.3.2.3.8 Note: Verify that the Waste Tray is fully seated in the Waste Drawer.

4.2.5.4 Loading & registering samples (Loading a sample without barcode):

4.2.5.4.1 Place the sample into the appropriate sample rack

4.2.5.4.2 Select the "Samples" menu to display the Samples screen

4.2.5.4.3 Select a rack from the diagram and touch "Load/Unload"

4.2.5.4.4 Open the Load Station Door

4.2.5.4.5 Load the appropriate samples rack with the uncapped sample without barcode

4.2.5.4.6 Close the Load Station Door.

4.2.5.4.7 The sample without barcode will be flagged as Error

4.2.5.4.7.1 Note: you can escape the steps from 4.2.5.4.3 to 4.2.5.4.7

4.2.5.4.8 Select the rack on the diagram

4.2.5.4.9 Touch the "Assign to Position" action button. The Assign to Position wizard displays

4.2.5.4.10 Open the Load Station Door

4.2.5.4.11 Select the sample position

4.2.5.4.12 Use the on-screen keyboard to enter the Sample ID twice.

4.2.5.4.13 Select the Sample Liquid Type, Select the profile

4.2.5.4.14 Touch Apply Sample

4.2.5.4.15 Close the Load Station Door.

4.2.5.4.16 Note: The system performs an inventory and automatically link the orders to the sample position.

4.2.5.5 Manually programming samples (How to make a test order):

4.2.5.5.1 Create an order:

4.2.5.5.1.1 Samples loading: as mentioned in 4.2.5.4

4.2.5.5.1.2 Select the sample for the order and touch the "Create Order" action button. Order settings are displayed for the sample ID you selected.

4.2.5.5.1.3 Review the 1st sample ID. This should be the sample ID you selected.

4.2.5.5.1.4 Touch the 1st Sample Liquid Type, and select the liquid type. The choices are:

4.2.5.5.1.4.1 Cent blood

4.2.5.5.1.4.2 Packed cells

4.2.5.5.1.4.3 0.8 cells

4.2.5.5.1.4.4 3 cells

4.2.5.5.1.4.5 Plasma

4.2.5.5.1.5 Review the Sample Location: the rack number and position.

4.2.5.5.1.6 Touch "Assigned Profiles" and select one or more from the profiles displayed. After selecting a profile, you can touch "Save and Start" to accept the remaining defaults and begin processing the order.

4.2.5.5.1.7 Notes:

4.2.5.5.1.7.1 Touch "Priority" if you wish to change Routine to STAT

4.2.5.5.1.7.2 Touch "Manual Rev. required" if you wish to change "No" (default value) to "Yes".

4.2.5.5.1.7.3 You can change any option by selecting it and making your change. Then touch "Save and Start". The system will process your order.

4.2.5.5.2 Re-run an order:

4.2.5.5.2.1 Select the "Samples" menu to display the Samples screen

4.2.5.5.2.2 Select the specific sample – this is also possible directly in the diagram view

4.2.5.5.2.3 Touch the "Create Order" action button

4.2.5.5.2.4 The selected sample ID is appearing per default according to the sample that has been selected

4.2.5.5.2.5 Touch "Assigned Profiles" and select the profiles to rerun.
4.2.5.5.2.6 Touch "Save and Start".

4.2.5.5.3 Modify an order:
4.2.5.5.3.1 Select the "Results" menu to display the Results screen
4.2.5.5.3.2 Select the specific sample – Status is "Waiting for sample (pending)"
4.2.5.5.3.3 Select the "Samples" menu to display the Samples screen
4.2.5.5.3.4 Touch the "Change View" action button
4.2.5.5.3.5 Touch the "Modify Order" action button
4.2.5.5.3.6 Select the order
4.2.5.5.3.7 Touch "Save"
4.2.5.5.3.8 Touch "Priority" if you wish to change Routine to STAT.

4.2.5.5.4 Create a batch order:
4.2.5.5.4.1 Samples loading: as mentioned in 4.2.5.4
4.2.5.5.4.2 Select the "Batch Order" action button.
4.2.5.5.4.3 Select the sample IDs for the batch order. "Select All" and "Deselect All" buttons are available
4.2.5.5.4.4 Select the Samples Liquid Type
4.2.5.5.4.5 Select the liquid type for the samples included in the batch order:
4.2.5.5.4.5.1 Cent blood
4.2.5.5.4.5.2 Packed cells
4.2.5.5.4.5.3 0.8 cells
4.2.5.5.4.5.4 3 cells
4.2.5.5.4.5.5 Plasma
4.2.5.5.4.6 Touch "Assigned Profiles" and select one or more from the profiles displayed. After selecting a profile, you can touch "Save and Start" to accept the remaining defaults and begin processing the batch order.
4.2.5.5.4.7 Notes:
4.2.5.5.4.7.1 Touch "Priority" if you wish to change Routine to STAT
4.2.5.5.4.7.2 Touch "Manual Rev. required" if you wish to change "No" (default value) to "Yes".
4.2.5.5.4.7.3 You can change any option by selecting it and making your change. Then touch "Save and Start". The system will process your order.

4.2.5.5.5 Create a cross match order:
4.2.5.5.5.1 Select the patient/recipient sample for the order and touch the "Create Order" action button
4.2.5.5.5.2 Touch the 1st Sample Liquid Type, and select the liquid type. The choices are:
4.2.5.5.5.2.1 Cent blood
4.2.5.5.5.2.2 Packed cells
4.2.5.5.5.2.3 0.8 cells
4.2.5.5.5.2.4 3 cells
4.2.5.5.5.2.5 Plasma
4.2.5.5.5.2.6 Note: Cent blood is the default for 1st Sample Liquid Type
4.2.5.5.5.3 Touch "Assigned Profiles" and select the cross match profile
4.2.5.5.5.4 Touch the "Add Donor Sample" button to assign the donor to the order. Fields are displayed to enter a donor ID and sample type:
4.2.5.5.5.4.1 Touch "Add Donor Sample" button again to add additional donors to the order.

4.2.5.5.5.5 If the fields to enter donor ID and Sample type are not displayed automatically, click the donor area on the screen to access the entries field.

4.2.5.5.5.6 Touch "Save and Start" to accept the remaining defaults and begin processing the order.

4.2.5.5.5.7 Notes:

4.2.5.5.5.7.1 Touch "Priority" if you wish to change Routine to STAT

4.2.5.5.5.7.2 Touch "Manual Rev. required" if you wish to change "No" (default value) to "Yes".

4.2.5.5.5.7.3 You can change any option by selecting it and making your change. Then touch "Save and Start". The system will process your order.

4.2.5.5.5.7.4 For a cross-match, multiple donors can be assigned to one recipient within a single order.

4.2.5.5.5.7.5 To assign a single donor to multiple recipients for a cross-match, you must create multiple orders.

4.2.5.5.5.7.6 The "Add Donor Sample" button becomes active when a profile is assigned that requires a cross-match test.

4.2.5.6 Results:

4.2.5.6.1 Manual Review: This option allows to resolve indeterminate results, when a test has been flagged for manual review, or if the system has been configured to require manual review for specific test. To access the cassettes in the Manual Load/Review rack in the Dual Purpose Drawer:

4.2.5.6.1.1 Select the "Resources" Menu button

4.2.5.6.1.2 Select "Manual Load/Review"

4.2.5.6.1.3 The Manual Load/Review screen is displayed. Touch the "Load/Unload" action button.

4.2.5.6.1.4 A wizard is displayed, allowing you to open the Dual Purpose Drawer and to unload cassettes

4.2.5.6.1.5 Close the drawer.

4.2.5.6.1.6 Touch "Results"

4.2.5.6.1.7 Select the profile to review

4.2.5.6.1.8 Select "Show Details"

4.2.5.6.2 Multiselect:

4.2.5.6.2.1 Touch "Disable Multiselect" to enable/disable the selection of multiple table rows. When multiselect is disabled, only one table row can be selected at a time. Multiselect is allowing to archive or to cancel multiple profiles at the same time.

4.2.5.6.3 Filter results: this allows filtering the results on the results screen.

4.2.5.6.3.1 Touch "Filter Disabled" and then select one or more of the filter options:

4.2.5.6.3.1.1 Pending

4.2.5.6.3.1.2 Processing

4.2.5.6.3.1.3 Cancelled

4.2.5.6.3.1.4 Aborted

4.2.5.6.3.1.5 Review Required (Completed)

4.2.5.6.3.1.6 Accepted

4.2.5.6.3.1.7 Rejected

4.2.5.6.3.2 Only the results applicable to the options you selected are displayed. When a filter is applied the button is becoming black "Filter Enabled".

4.2.5.6.3.3 Touch "back" to return to the Results screen.

4.2.5.6.3.4 To remove the filters, touch "Filter Enabled" and deselect all filter options.

4.2.5.6.3.5 Touch "back" to return to the Results screen and display all current results.

4.2.5.6.4 Results details:

4.2.5.6.4.1 In the "Results" menu, select a result or a profile

4.2.5.6.4.2 Select "Show Details"

4.2.5.6.4.3 The image(s) of the cassette(s) are presented on the screen with different options, including:

4.2.5.6.4.3.1 Changing the color of the image from grey scale to color

4.2.5.6.4.3.2 Changing cassette view

4.2.5.6.4.3.3 Use the Zoom option to display an image on a larger scale

4.2.5.6.5 Different results procedures are available according to individual and laboratory settings:

4.2.5.6.5.1 Display columns on a larger scale (zoom):

4.2.5.6.5.1.1 Select a column image to open a details view with an enlarged image of the selected column.

4.2.5.6.5.1.2 The column images are shown in grey and color for both sides of the cassette

4.2.5.6.5.2 Changing Image to Color or Greyscale:

4.2.5.6.5.2.1 The image is displayed in greyscale

4.2.5.6.5.2.2 Select "Change to Color" button

4.2.5.6.5.2.3 The color image is displayed and the button becomes "Change to Grayscale".

4.2.5.6.5.3 Change cassette view

4.2.5.6.5.3.1 You can view either side of tested cassettes.

4.2.5.6.5.3.2 Touch the "Change to Back" action button.

4.2.5.6.5.3.3 The reverse side of the cassette is displayed, and the button becomes "Change to Front"

4.2.5.6.5.4 Accept Results:

4.2.5.6.5.4.1 Results requiring manual review must be accepted or rejected.

4.2.5.6.5.4.2 Touch the "Results" menu button

4.2.5.6.5.4.3 Select the profile to review

4.2.5.6.5.4.4 Touch the "Show Details" action button.

4.2.5.6.5.4.5 Review the result prior to accepting.

4.2.5.6.5.4.6 Touch the "Accept Result" action button.

4.2.5.6.5.4.7 When a result has been accepted, the status will change to "Accepted" in the window on the Details screen.

4.2.5.6.5.4.8 Note: Accepted results cannot be edited.

4.2.5.6.5.5 Reject Results:

4.2.5.6.5.5.1 Results that are not automatically accepted must be reviewed before they can be accepted or rejected.

4.2.5.6.5.5.2 Touch the "Results" menu button.

4.2.5.6.5.5.3 Select the profile to review.

4.2.5.6.5.5.4 Touch the "Show Details" action button.

4.2.5.6.5.5.5 Review the results before rejecting the result.

4.2.5.6.5.5.6 Touch the "Reject Result" action button.

4.2.5.6.5.5.7 The "Rejected Result" icon appears next to this result on the Details screen.

4.2.5.6.5.6 Edit a Column Grade (Modify)

4.2.5.6.5.6.1 The "Edit Grades" action button is enabled if all test analysis results are available and the test has not yet been accepted.
4.2.5.6.5.6.2 Touch the "Results" menu button.
4.2.5.6.5.6.3 Select the profile to edit
4.2.5.6.5.6.4 Touch the "Show Details" action button.
4.2.5.6.5.6.5 The result appears with the picture of the cassette
4.2.5.6.5.6.6 Touch the "Edit Grades" action button. A new window appears
4.2.5.6.5.6.7 Select the column with the grade you wish to edit.
4.2.5.6.5.6.8 If scanning the barcode is required, scan the barcode for the cassette.
4.2.5.6.5.6.9 Touch the grade for the column you wish to edit. Alternative grades are displayed.
4.2.5.6.5.6.10 Select the grade you want for that column.
4.2.5.6.5.6.11 The grade you selected now appears as the grade for that column. An asterisk indicates the edit.
4.2.5.6.5.6.12 Touch "Next"
4.2.5.6.5.6.13 Add a comment if this is required.
4.2.5.6.5.6.14 Touch "Next"
4.2.5.6.5.6.15 Enter your password and touch "Confirm Password".
4.2.5.6.5.6.16 Select "Accept result"

4.2.5.6.5.7 Edit results (Modify)
4.2.5.6.5.7.1 Test results can be edited only when all results are available and the test has not been accepted.
4.2.5.6.5.7.2 Touch the "Results" menu button.
4.2.5.6.5.7.3 Select the results you wish to edit and touch the "Show Details" action button.
4.2.5.6.5.7.4 Touch the "Edit Results" action button. A three-screen wizard opens.
4.2.5.6.5.7.5 Select the result you wish to edit, select a "new result" and touch "Next".
4.2.5.6.5.7.6 Enter a comment describing your change and touch "Next".
4.2.5.6.5.7.7 Enter your password and touch "Confirm Password".
4.2.5.6.5.7.8 Select "Accept result"
4.2.5.6.5.7.9 Your edited result is reflected in the Results-Details screen, marked with an asterisk indicating a modified result.

4.2.5.7 Flags and codes:
4.2.5.7.1 The table (in annex 1) displays Result Values. Results Values are shown on the Results screen, printed on reports, and included on Log files.
4.2.5.7.2 Results flag information identifies results that are above or below the reportable range.
4.2.5.7.3 Codes indicate conditions that require operator attention.

5. MATERIALS AND EQUIPMENT:

5.1 As mentioned for each test.

6. RESPONSIBILITIES:

6.1 Blood bank staff members like technician/ specialist have to follow the detailed procedures.

7. APPENDICES:

7.1 ANNEX 1 – flags & codes

8. REFERENCES:

8.1 Micro Typing systems, version 2.0, publication number J32851_EN, 2008.
8.2 ORTHO BioVue® System Handbook, J55888EN
8.3 Quick Guide ORTHO VISION® Analyzer (software version 4.8.0).
8.4 ORTHO VISION™ Analyzer BioVue Cassettes Reference Guide J55655 .

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Mohammed Amer	Blood Bank Physician		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 13, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025

Appendix 7.1

ANNEX 1 – FLAGS & CODES

Codes indicate conditions that require operator attention. For example, if a lot change occurs during a test, the system assigns code '?' to the result to call attention to the lot change. The table below displays Result Values. **Results Values** are shown on the Results screen, printed on reports, and included on Log files. If a result code is frequent, contact your Customer Technical Support. Always refer to the Instructions for Use and the Reference Guide for additional information.

Result Code	Acronym Definition	Column Interpretation	Conditions	Suggested Actions
0	NA	Negative	NA	Follow your laboratory Standard Operating Procedures.
0,5+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
1+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
2+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
3+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
4+	NA	Positive	NA	Follow your laboratory Standard Operating Procedures.
U	Unknown	No result reported	The system received a result from the IMAGINGSYSTEM that wasnot interpretable.	Rerun the test.
CNF	Column Not Found	If the correct location could not be ensured during the reprocessing 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 CASSETTE 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 Cassette and load the cassette in the MANUA REVUIEW RACK to be reused. If the correct location could not be found during the post processing check, manually read the reaction.
WLL	Wrong Liquid Level	No Result Reported	The IMAGING SYSTEM could not confirm that the volume of liquids 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 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 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 debris on the Cassette, or there was not enough sample serum/plasma and patient red blood cells (RBCs) were aspirated instead of serum/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 Cassette. Clean the debris from the surface of the Cassette and perform a manual read of the column.Check the sample container and if the serum/plasma has been depleted; Rerun the test using a new sample.
LTH	Light Too High	No Result Reported	The light between the columns is checked with every read ; the adjacent light level read was too high.	Inspect the cassette for holes or reflective debris, and manually read the reactions. If the result code is frequent, you may need to clean or adjust the CASSETTE IMAGING SYSTEM.
CI	Contrast Interference	No Result Reported	The liquid in the column above the media was dark and the IMAGE 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.
NC	No Cells	No Result Reported	The IMAGING SYSTEM found that there were no cells or almost no cells in the column.	You may have 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.	You may have insufficient volume of reagent or sample, or reagent red blood cells (RBCs) may not have been properly suspended. Check the reagent vials and replace reagents if necessary. Rerun the tests.
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 (RBCs) may not have been properly suspended. RBCs may have evaporated, or there was not enough sample plasma/serum and patient red blood cells were aspirated instead of plasma. If you suspect RBCs have been compromised due to improper suspension or evaporation (exceeded on board stability), discard all vials from that set and replace with a new set. Re-suspend the reagents and rerun the tests. If you suspect the sample is the source of the TMC code, make sure there is adequate plasma volume and rerun the test. Re-centrifuge 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 column; 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 is 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 distribution which may have been caused by fibrin in the sample.	Rerun the test or manually interpret the reaction following your laboratory Standard Operating Procedures.
BUB	Bubble	If a bubble is found during the pre-processing 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 IMAGING 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 are not correct in the pre-processing check, the cassette 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 CASSETTE IMAGING SYSTEM.	Inspect the focus targets for debris and clean them if necessary.
PE	Position error	No Result Reported	The CASSETTE IMAGING SYSTEM has determined that the cassette 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 pre-processing 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 cassette before it was used and automatically ran the test using another cassette. Refer to the cassette IFU to determine proper disposition of the cassette.
CND	Cassette not detected	No Result Reported	The CASSETTE IMAGING SYSTEM has determined that the cassette is not properly positioned or 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:

1. Accepted/Rejected
2. Transferred to LIS
3. Instrument simulated
4. Result edited by user

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

1. Result expired
2. Errors from imaging system
3. QC expired
4. Lot expiration
5. Sensor reading temperature dropping out of the notification range
6. Sensor reading humidity dropping out of the notification range
7. Maintenance expired/failed
8. Edited results