

## Updates to the Imaging System and Results Flags and Codes

### 1 Purpose

This Technical Bulletin provides important information regarding the Imaging System and Results Flags and Codes for ORTHO VISION® and ORTHO VISION® Max Analyzers for ID-MTS™ Gel Cards.

### 2 Applicability

This Technical Bulletin is applicable for both the ORTHO VISION® and the ORTHO VISION® Max Analyzers for ID-MTS™ Gel Cards.

### 3 Changes to User's Guide

The next version of the ORTHO VISION® Analyzer – ID-MTS™ Gel Cards Reference Guide (J40050EN) and ORTHO VISION® Max Analyzer – ID-MTS™ Gel Cards Reference Guide (J55656EN) will be revised as follows:

- **Chapter 3 System Components - Section: Imaging System: -**

**Existing Content:**

The Imaging System captures multiple images of the agglutination reactions and then analyzes the images to produce test results. The Card images and test results are displayed through the user interface (Results).

The Imaging System also performs positive identification and a quality check of all Cards before they can be used for test processing.

**Revised Content:**

**IMPORTANT: For additional information on visually inspecting Cards, refer to the ID-Micro Typing System™ Interpretation Guide and the Instructions for Use.**

The Imaging System performs positive identification and a quality check of all Cards before the system uses them for test processing. The Imaging System captures multiple images of the agglutination reactions and then analyzes the images to produce the test results. The images and the test results display on the user interface (Results).

When the system determines a Card contains an artifact that may interfere with test performance, the system rejects the Card prior to processing and moves it to the Manual Review Rack. If the Manual Review Rack is full, the system places the Cards in the Waste Drawer. If the system rejects three consecutive Cards from a sleeve, it will reject the entire sleeve.

**Note: If a user places a Card in the Load Area of the Dual-Purpose Drawer and the system identifies unacceptable columns on the Card, the system may still process the acceptable columns. The system will not use columns identified as unacceptable.**

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- **Chapter 10 Results- Section: Flags and Codes: -**

**Existing Content:**

<b>Result Code</b>	<b>Acronym Definition</b>	<b>Column Interpretation</b>	<b>Conditions</b>	<b>Suggested Actions</b>
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 or during the pre- processing quality check, the IMAGING SYSTEM detected that the foil above the column may have already been punched.	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 Instructions For Use to determine proper disposition of the Card.

**Revised Content:** The CVE result code will be removed from this chapter.

**Rationale for Removal:** Column Volume Error (CVE) is not a Result Flag or Code reported by the system. If the system detects an incorrect supernatant and/or gel level during the preprocessing quality check, or compromised foil above a column, the system reports a "Cims72 — Wrong Fluid Volume" error.

No results are associated with a Card that fails the preprocessing quality check since the system rejects the impacted Card.

## 4 Storing this Bulletin

Place this bulletin in the front of ORTHO VISION® Analyzer – ID-MTS™ Gel Cards Reference Guide (J40050EN) and ORTHO VISION® Max Analyzer – ID-MTS™ Gel Cards Reference Guide (J55656EN). The instructions listed in this bulletin supersede those stated in the Reference Guide.

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