

November 22, 2022

Updated Interpretation Guide for ID-Micro Typing System™ (MTS)

Dear Valued Customer,

At Ortho Clinical Diagnostics, we are committed to providing you with continuously improved products and services. Through engagement with our customers (like you) for insight on how to improve our services, Ortho has captured feedback on how we can improve visual aids and added descriptive directions on interpreting the acceptable appearance of Gel Card prior to use. Our internal performance testing results from these suggestions were incorporated into the ID-MTS Interpretation Guide to provide those improvements.

Ortho is pleased to announce an extensive update to the Interpretation Guide for ID-Micro Typing System™.

Obtaining the Guide

To access and download the Interpretation Guide, please visit our Technical Documents Library at <https://techdocs.ocdx.com> and **log in**.

Publication Name	Publication Number
ID-MTS Interpretation Guide	6902201

If you'd like to obtain a physical copy, please contact your Ortho representative.

Key Updates

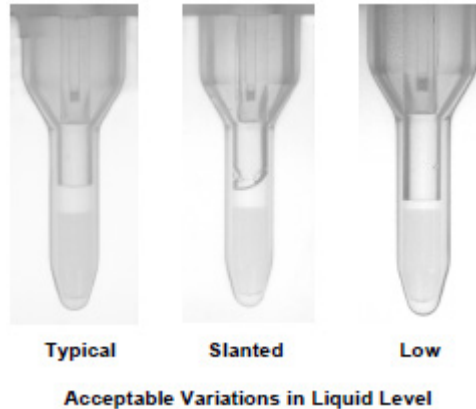
The following content in **Chapter 2: Visual Inspection of Gel Cards Prior to Use** of the ID-MTS Interpretation Guide is summarized below.

To view all changes please refer to the Revision History section of the Interpretation Guide.

- Chapter 2 is organized to describe and provide examples of acceptable microtubes, unacceptable microtubes, and overall acceptability of gel cards prior to use. Example images of gel cards were updated to also include those generated by the ORTHO VISION® and ORTHO VISION® Max Analyzer during the card pre-processing quality check.

Key Updates Cont'd

- Page 2-1 (PDF Page 9): Gel cards with low liquid layer (and no other artifacts present) are considered acceptable for use but should be carefully examined. The following are examples of acceptable variations in liquid level.



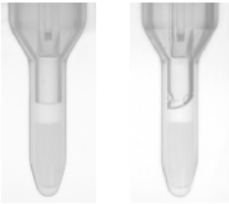
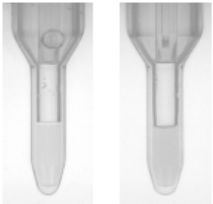

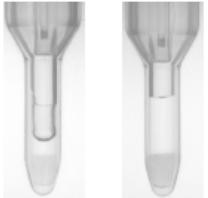
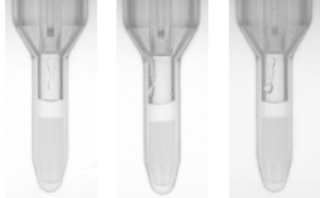
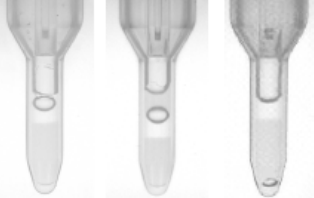
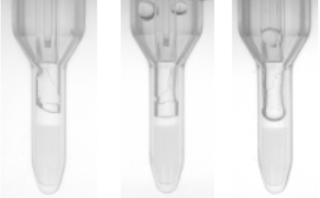

- Page 2-2 (PDF Page 10): Gel cards with liquid drops (previously referenced as splash) above the liquid layer are acceptable for use. If liquid drops are observed with additional artifacts (e.g., no liquid layer, low (or no) gel layers, signs of drying (dried/cracked gel) or bubbles in the liquid/gel layer) refer to the **Unacceptable Microtubes** section of the guide. [This change in acceptability of gel cards with liquid drops above the liquid layer \(splash\) compared to prior revisions of the ID-MTS Interpretation Guide that advised against use of gel cards exhibiting this visual characteristic is supported by additional performance testing conducted by Ortho.](#)

The following are examples of microtubes with liquid drops above the liquid layers that are acceptable for use:



**Key Updates
Cont'd**

Page 2-5 (PDF Page 13): A table was added to summarize the acceptability of gel cards prior to use to better guide the visual inspection process.

Acceptable for Use	Unacceptable for Use
<p>Microtube with a clear liquid layer above the gel matrix.</p> 	<p>Liquid layer in microtube is at or below the gel matrix.</p> 
<p>Variations in the liquid and or gel level between microtubes.</p>  <p style="text-align: center;">All Acceptable</p>	<p>Low gel level that occupies less than half the microtube.</p> 
<p>Residue with visible liquid layer above gel matrix.</p> 	<p>Bubbles trapped in the liquid layer or within the gel.</p> 
<p>Liquid drops above the liquid layer without additional artifacts.</p> 	<p>Dried or cracked gel. May be observed with or without liquid present.</p> 

**Updated
Shipping**

In addition, to minimize the receipt of unacceptable gel cards due to in-transit shipment handling, Ortho has relocated the foam insert of the 100 count shippers from the bottom of the unit (under the sleeved cards) to the top (over the sleeved cards).

**Contact
Information**

If you have questions, please contact our Ortho Care™ Technical Solutions Center at 1-800-421-3311.