

Manufacturer and Product Information

Diamond Diagnostics, 333 Fiske Street, Holliston, MA.
For Technical Assistance call:
 Diamond Diagnostics Technical Services at 1-508-429-0450

Introduction and Intended Use:

Hct is an assayed bi-level quality control material intended for monitoring the measurement of hematocrit on analyzers as shown in the *Expected Value Charts*. There are two levels of Hct, each provided in 2.0 mL ampules. The two levels allow verification of analyzer performance in the low and mid clinical ranges.

Summary And Principle: This product is intended to serve as a functional equivalent to pre existing material distributed by the Original Equipment Manufacturers (OEMs).

Reagents: Hct Level B, CD-570406D

Containing: Hct Level B, CD-570406D are aqueous bicarbonate solutions with other salts and preservatives.

For In Vitro diagnostic use only

Storage and Handling: Store Hct B at 18 to 25°C. Refer to the label on each ampule and on the box for the expiration date.

Instructions for Use
Instructions for Use

1. Before use, hold the ampule by its tip and shake it vigorously for 10 seconds.
2. Tap the liquid back into the base of the ampule
3. Open the ampule by snapping off the tip at the score. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
4. Sample the contents of the ampule according to the recommended technique provided by the analyzer manufacturer. For optimal results, use a single sample containing at least 0.5 mL.
 - Direct Aspiration- Sample the control directly from the ampule.
 - Syringe Transfer- Aspirate contents of the ampule into a syringe fitted with a blunt needle (if available). Expel any air bubbles by discarding a portion of the control into a tissue. Carefully detach the needle, and sample in the QC mode according to the recommended technique provided by the analyzer manufacturer. For optimal results, use a 3-5 mL syringe (maximum) and a 20 gauge needle (minimum).
5. Record the results according to the quality assurance program established for your laboratory.

Limitations
Expected Analyzer Performance:

The values in the Expected Values Chart are based on multiple determinations performed on randomly selected samples from each lot. Diamond Diagnostics controls are measured side by side with OEM controls to ensure product performance.

Expected Values:	Instrument	348	Rapidpoint 400
	Hematocrit	48.0%	45.0 %
	Range	45.6% - 50.4%	42.8% - 47.2%

Limitations: If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following:

1. Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination.
2. Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.
3. Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.
4. If problems still exist, contact Diamond Diagnostics' Technical Service Department.

