Lab Name: **Procedure #:**

Procedure: CLIA Complexity: WAIVED

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedural Bulletin is intended to provide a ready outline reference for performance of the assay. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP2-A2.

Diagnostic Test Group provides CLSI procedures for your use. The procedures are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

Lab Name:

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INTENDED USE

Clarity One step Immunological Fecal Occult Blood Test is a rapid convenient and odorless qualitative, sandwich dye conjugate immunoassay for the determination of human hemoglobin in feces and is a useful aid in the diagnosis and therapy of gastrointestinal disorders.

PRINCIPLE OF THE TEST

After application of the sample it moves to a pad coated with antibody colloidal-gold-conjugates by capillary action. In the event of a positive sample the hHB binds to the corresponding anti- β-hHB antibody colloidal gold conjugate and the complex moves on to a line constituting immobilized anti-α -hHB antibodies. In the presence of hHB a purple line appears in the reaction area at “T”. As an internal positive control at the pad of antibody-colloidal-gold-conjugates another independent antibody colloidal- gold-conjugate is mobilized and independent of the presence of hHB moves to another immobilized antibody. This results in a purple color line at “C” and serves as a control for the correct test performance.

REAGENTS AND MATERIALS SUPPLIED

- 30 foil pouches each containing 1 test cassette and 1 desiccant
- Instruction for use
- 30 sample collection tubes with buffer
- 1 Vial of Negative control
- 1 Vial of Positive control

MATERIALS REQUIRED BUT NOT PROVIDED

- A timer, Sample Container and disposable gloves.
- No other equipment or reagents are needed

WARNINGS AND PRECAUTIONS

- In vitro diagnostic device for professional use
- For external use only
- Keep out of reach of children

- Do not use the tests after expiration date
- Read instructions for use carefully
- Open foil pouches just prior to use, use each test cassette just once
- Do not take apart test cassettes
- Do not ingest sample buffer (or other portions of the test)
- Patients' samples could be infected and as such should be handled and disposed of as potentially infectious
- Do not smoke, drink or eat while performing the test
- Wear gloves and wash hands after performing the test
- Avoid spilling, splashing, dissipation and the like
- Observe the given incubation times, otherwise the sensitivity or specificity of the test may be influenced

KIT STORAGE AND STABILITY

Clarity IFOBT Rapid Test Device test kit should be stored at 2°–30°C (36°–86°F) in its sealed pouch. Do not freeze.

SPECIMEN COLLECTION AND STORAGE

Specimen:
The specimen to be used is stool. Generally, one stool specimen will be collected by the patient himself (either at home or testing location). The sampling has to be performed according to the instructions included for the patient, which must be passed on to the patient. If the specimen is to be stored by the patient for any length of time before testing, please provide a Clarity Mailer for hygienic storage and transportation of stool sample.

ATTENTION: Please inform the patient as to the quantity of specimen needed as too much can result in test performance problems.

Storage of specimens:
Specimens collected may be stored up to 6-8 days at 98.6 °F(37°C) ,Six Months at 39.2 °F (4°C) and at least 20 months at -4 °F (-20 °C)

TEST PROCEDURE

Put on gloves before performing the following steps.

Test performance:

1. Bring the specimen to 20-25°C (68-77°F).
2. Open foil pouch just prior to use.
3. Shake the sample collection tube in order to ensure proper mixing of the stool Specimen with the sample buffer. Open the tip cover of the sample collection tube and Squeeze tube to dispense 3 drops in to the sample well.
4. Then wait 5 minutes.

INTERPRETATION OF RESULTS

Positive Result:

If both a C-line and a T-line are present, the result is positive. One Purple Colored horizontal band each at the Test position (T) and at the Control Position (C) indicates a positive result.

Note:

A positive test result may be read as soon as a distinct purple colored band appears at the **Test position (T)** and at the **Control position (C).**Any shade of purple colored horizontal band at the **Test position (T)** should be reported as a positive result. The intensity of the colored band at the **Test position (T)** may be different from the intensity of the band at the **Control position (C).**

Negative Result:

If only the C-line develops in the control region of the test strip, the result is negative. One pink-purple colored band at the **Control position(C),** with No distinct colored horizontal band at the **Test position (T)** other than the Normal faint background color indicates a negative result.

Invalid Result:
If no C-line appears within 5 minutes, the result is Invalid and the assay should be repeated with a new device. A distinct colored horizontal band at the **Control position (C)** Should always appear. The test is invalid if no such band Forms at the **Control position (C).**

QUALITY CONTROL

There are two internal control features in **Clarity** IFOBT Rapid Test Device. A colored control band will always appear at the **Control position (C)** if the test has been performed correctly and if the device is working properly. This is considered an internal positive procedural control. A clear background in the result window is considered an internal negative procedural control. If the test has been performed correctly and **Clarity** IFOBT device is working properly, the background in the result window will be clear, providing a distinct result.

Good laboratory practice recommends the periodic use of external control materials to ensure proper kit performance. The included positive and negative controls can be run in place of stool specimen according to the test procedure for this purpose. If the controls do not perform as expected or the colored control band does not appear at the **Control position (C)**, contact Diagnostic Test Group Technical Services immediately for assistance at 1-877-485-7877.

LIMITATIONS

- The Clarity one step immunological Fecal Occult Blood test is a valuable aid in the early detection of gastro intestinal bleeding device. However, since bowel lesions, including some polyps and colorectal cancers, may not bleed at all or may bleed intermittently, or the blood may not be uniformly distributed in a fecal sample, a test result may be negative even when a disease is present.
- The Clarity One Step Immunological Fecal occult blood test results may be positive for samples from healthy patients. This may be because certain medications may cause gastrointestinal irritation resulting in occult bleeding.
- As with any occult blood test, Clarity One step Immunological Fecal Occult blood test may not be considered as a conclusive diagnostic for gastro intestinal bleeding or pathology, they can only be regarded as a preliminary screening or as an aid to diagnosis. They are not intended to replace other diagnostic procedures such as G.I.Fibroscope, Endoscopy , colonoscopy and other X-ray studies

EXPECTED VALUES

Analytical sensitivity:
Clarity IFOBT show a positive results starting with an Hhb concentration of 0.05 µg/mL (corresponds to about 0.03 mg/g stool). Also a very faint line at "T" has to be judged as positive result.

Specificity / Cross-reactions
Clarity IFOBT is specific for human hemoglobin.

The following substances do not influence the test results:

Substance	Concentration
Chicken – Hemoglobin	500µg/mL
Pig – Hemoglobin	500µg/mL
Beef – Hemoglobin	2000µg/mL
Sheep – Hemoglobin	500µg/mL
Horse – Hemoglobin	500µg/mL
Rabbit – Hemoglobin	500µg/mL
Horseradish Peroxidase	2000µg/mL

ASSISTANCE

If you have any questions regarding the use of this product, please call Diagnostic Test Group Technical Support number, (877) 722-6339, Monday through Friday, between 8:00 a.m. and 6:00 p.m. Eastern Standard Time, U.S.A.

REFERENCES

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IVD

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Lab Name:

LOG SHEET

Record Built-in Procedural Controls on the first patient tested each day.

	Date	Patient Name	Positive Procedural Control (Purple Line)	Test Results At 5minutes Do not read the test results after fifteen (10) minutes	Lot Number and Exp. Date	Technician
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

LOG SHEET

	Date	External Positive Control Result	External Negative Control Result	Lot Number and Exp. Date	Technician
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					