

<b>REF</b>	03-06-0070	30 Tests
<b>REF</b>	03-06-0071	60 Tests
<b>REF</b>	03-06-0072	90 Tests

Pour d'autres langues  
Für andere Sprachen  
Para otras lenguas  
Per le altre lingue  
Dla innych języków

Para outras línguas  
Για τις άλλες  
Λόσσες  
För andra språk  
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[www.trinitybiotech.com](http://www.trinitybiotech.com)

## INTENDED USE

The Tri-stat Reagent Kit for use with the Tri-stat Analyzer is a rapid *in vitro* diagnostic test for measurement of the percent of glycated hemoglobin (% HbA1c and mmol HbA1c/mol Hb) in human blood from finger stick or venous samples for clinical laboratory and point-of-care use. Measurement of percent HbA1c is used to monitor long-term glucose control in individuals with diabetes mellitus.

For *in vitro* diagnostic use only. **IVD**

## PRINCIPLE OF THE PROCEDURE

The reagent tube contains boronate affinity gel. A finger stick, venous blood, or control sample is collected with a capillary and added to the reagent tube. In the instrument, the sample is mixed with the suspended gel particles, releasing HbA1c from the red blood cells. After calculations and validation, the HbA1c test value is displayed on the display screen.

## TEST KIT COMPONENTS

Each Tri-stat Reagent Kit Includes –	<b>REF</b>	03-06-0070	03-06-0071	03-06-0072
		QTY	QTY	QTY
• Reagent Tubes – (containing buffer solution, gel and fluorescent dye)		30	60	90
• Integrated Collection Capillaries (ICC) – EDTA treated capillary & cap for blood collection		30	60	90
• Reagent Tube Tray(s)		1	2	3
• Key Card		1	1	1
• Package Insert		1	1	1

## STORAGE

- Store refrigerated in an upright position at 2°C - 8°C (35°F - 46°F).
- **DO NOT FREEZE.**
- Store the reagent tubes in original tube trays placed inside supplied kit box with box lid closed to minimize light effects and prolong stability of the reagents. Ensure that the reagent tubes are not exposed to direct light for prolonged periods of time as this may affect the fluorescent dye properties.



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## STORAGE

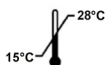
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## PRECAUTIONS

- Reagent tubes cannot be used after the expiration date.
- In the event of shipping damage, do not use reagent tubes that are broken, leaking, or irregular.
- Reagent tubes must be used at room temperature or 15°C to 28°C (59°F - 82°F).
- The test should be performed at room temperature or 15°C to 28°C (59°F - 82°F).
- Avoid using the instrument in direct sunlight or prolonged light exposure.
- Follow appropriate biohazard procedures when handling and disposing of samples and blood collection materials.
- For *in vitro* diagnostic use only. Avoid contact with skin. May be harmful by ingestion, inhalation or if absorbed through the skin. Refer to the Safety Data Sheet "Tri-stat Reagent Kit" for detailed information.



## SPECIMEN COLLECTION AND HANDLING

- Sample must be collected in the ICC (Integrated Collection Capillary) provided.
- The capillary must be filled completely with fresh whole blood ONLY.
- Ensure that no excess blood clings to the outside of the capillary and no air bubbles are visible in the filled capillary. Discard the ICC if sampling error occurs and resample using a new ICC.
- Close the reagent tube immediately after adding sample to the capillary by inverting the ICC as per test procedure instructions.
- Ensure that no reagent spills from the tube when adding sample and handling. If reagent spills from the tube, discard the tube and use a new one to repeat the test.
- Start the test within three (3) minutes of sample collection. The capillary is treated with an anti-coagulant, but blood will still clot if the sample is not used within three (3) minutes. If the blood clots in the capillary, the sample is NOT usable. In such a case, discard the reagent tube and collect a new sample for testing.

## TEST PROCEDURE

Refer to the Quick Reference Guide or to the Operator's Manual for further details.

## ORDERING INFORMATION

Catalog No.	Item	Quantity
03-06-0070	Tri-stat Reagent Kit (30)	30 Tests
03-06-0071	Tri-stat Reagent Kit (60)	60 Tests
03-06-0072	Tri-stat Reagent Kit (90)	90 Tests



Trinity Biotech  
Kansas City, MO 64132 USA  
Tel. 1 800-325-3424  
Fax: 1 816-361-1974



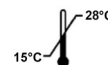
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## TEST PROCEDURE

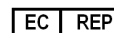
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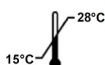
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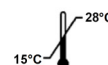
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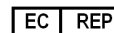
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