

Sun Diagnostics Rapid Biotin Assay Instructions for Use

The Sun Diagnostics Biotin Assay Kit is designed to measure elevated Biotin concentrations (and its metabolite Biotin Sulfoxide) in human serum that may interfere with immunoassays. The Sun Diagnostics Rapid Biotin Assay Kit is for Research Use Only.

Kit Components: (store at 2-8° C unless otherwise noted)

Neutravidin-coated microtiter plate (12 x 8 well strips)
Assay calibrator set, five levels (0, 25, 50, 100 and 200 ng/mL serum biotin)
Assay Controls (Low, Medium, High serum biotin)
10X Wash buffer solution
Sample diluent (ready to use)
Biotin-HRP conjugate (400X)
TMB substrate (ready to use)
Stop solution (ready to use)
Plate sealant tape

Items Not Supplied:

Pipettes, tips and other lab consumables
Multichannel pipettor (w/ 300 µL Capacity)
Rotator platform (300 rpm capability)
Plate reader (450 nm and 650 nm capability)
Reagent troughs

Precautions/Warnings

Exercise universal precaution with use of proper personal protective equipment when working with human serum samples. The Stop Solution contains an inorganic acid. Exercise precaution when working with this solution.

WARNING: Potentially Bio-hazardous

Human source material is considered potentially bio-hazardous. This material was tested for communicable diseases (HIV, Hepatitis B and Hepatitis C) with kits approved by the FDA (where available) and found to be negative (non-reactive). Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

Dispose of all waste material in accordance with requirements of your local waste management authorities

Before use, allow all reagents, calibrators and samples to reach room temperature (18-25 ° C). Protect from long periods of light exposure.

Storage/Stability

This product is stable until the expiration date provided on the label. After use, promptly return to the proper storage condition.

Recommended Procedure

- 1) Remove the plates, reagents, calibrators, quality control and samples from storage and allow them to reach room temperature (20°-26° C).
- 2) Load each sample, quality control, and calibrator at 100 µL per well in duplicate and seal the plate with plate sealant tape. Incubate for 30 minutes at room temperature (20°-26° C) with 300 RPM rotation on a shaker platform.
- 3) Decant the contents of the plate and blot onto a paper towel.
- 4) Prepare 100 mL working wash solution by adding 10 mL 10X wash solution in a 100 mL graduated cylinder and QS to 100 mL with Clinical Laboratory Reagent Water. Add 300 µL working wash solution to each well of the assay plate and decant after washing. Repeat 3 times for a total of 4 washes. Blot plate dry on paper towel after the last wash.
- 5) Prepare 15 mL of Biotin-HRP Working Solution by adding 37.5 µL 400x stock solution to 15 mL conjugate diluent.
- 6) Add 100 µL of the final 1:1.2M dilution of biotin-HRP to each well of the assay plate. Incubate for 30 minutes at room temperature (20°-26° C) with 300 RPM rotation on a shaker platform.
- 7) After incubation, decant the contents of the plate and blot onto a paper towel.
- 8) Add 300 µL working wash solution to each well of the assay plate and decant after washing. Repeat 3 times for a total of 4 washes. Blot plate dry on paper towel after the last wash.
- 9) Add 100 µL/ well TMB substrate to each well and incubate for precisely 5 minutes (no platform rotation necessary).
- 10) Stop the colorimetric reaction with the addition of 100 µL Stop Solution to each well.
- 11) Read plate at 450 nm or at 450 with a blank at 650 nm.
- 12) Standard curve is best fitted using a 4 or 5 parameter log-logit curve.



RAPID BIOTIN ASSAY

Performance Characteristics

Limit of Blank (LOB): 13 ng/mL

Limit of Detection (LOD): 32 ng/mL

Linearity: 0-200 ng/mL

Precision:

	Low QC	Med QC	High QC
Mean	35.0 ng/mL	86.3 ng/mL	175 ng/mL
Within-Run Precision (Repeatability)	3.0 ng/mL (8.6%)	5.2 ng/mL (6.0%)	4.1 ng/mL (2.3%)
Total Precision (Within-Device)	4.6 ng/mL (13.2%)	10.2 mg/mL (11.9%)	7.4 ng/mL (4.2%)

Assay Interference:

Interference screening was performed and no interference was seen for lipemia (up to 1000 mg/dL triglycerides), hemolysis (up to 570 mg/dL hemoglobin), icterus (up to 31 mg/dL conjugated bilirubin and up to 38 mg/dL unconjugated bilirubin), protein (up to 11 g/dL), HAMA (up to 1:640 titer), and RF (up to 982 IU/mL).

Assay Limitations

This product is for research use only.

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