TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	5/17/2018
Department:	Core Lab	**Due Date:**	6/17/2018
		Implementation:	**5/23/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Ketone (β-Hydroxybutyrate) Test using STAT-Site Mβ-HB Meter sGAH.C931 v1

This has been converted to a system SOP

Description of change(s):

Most changes are to make SOP match practice or format updates

Section	Reason
Header	Add other sites
4,6	Remove individual section labeling instructions and add general one
6.6	Qualify use of patient samples for new lots testing
7.2	Change freezer range to match practice
10.5	Move patient review from section 6
10.6	Remove supervisor notification
15	Update to new standard wording, move hazard statement from section 4
17	Update PI dates
Add 2	Add lint-free cloth for cleaning

This revised SOP will be implemented on May 23, 2018

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Ketone (β – Hydroxybutyrate) Test using STAT-Site M$^{β-HB}$ Meter**
Prepared by	Ashkan Chini Date: 5/16/2016
Owner	Robert SanLuis Date: 5/16/2016

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

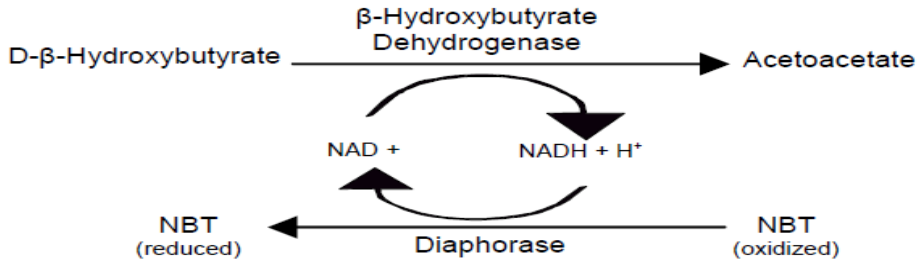
Assay	Method/Instrument	Local Code
Ketone (β – Hydroxybutyrate) Test	STAT-Site M$^{β-HB}$ Meter	BKETN

Synonyms/Abbreviations
Blood Ketone, Acetone, Beta Hydroxybutyrate

Department
Chemistry

2. ANALYTICAL PRINCIPLE

The STAT-Site M$^{β-HB}$ test measures β-Hydroxybutyrate using the principles of reflectance photometry. Through coupled enzyme reactions, the β-Hydroxybutyrate is oxidized, and the indicator NBT is reduced. The reflectance of the reduced NBT is measured at 580 nm and is mathematically converted into the β-Hydroxybutyrate concentration reported by the meter.



3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	N/A
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Serum Plasma (Lithium Heparin)	
Collection Container	Serum: Red top tube, Serum separator tube (SST) Plasma: Mint green top tube (PST)	
Volume - Optimum **- Minimum**	1.0 mL 0.5 mL	
Transport Container and Temperature	Collection container or Plastic vial at room temperature	
Stability & Storage Requirements	Room Temperature:	8 hours
	Refrigerated:	24 hours
	Frozen:	Not recommended

Criteria	
Timing Considerations	The time required for the test is less than 80 seconds.
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top or SST to clot completely prior to centrifugation.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
β – Hydroxybutyrate Test Strips	STANBIO Laboratories, Cat. No. 401010
STAT - Site Diluent	STANBIO Laboratories, Cat. No. 202000

4.2 Reagent Preparation and Storage

Reagent	β – Hydroxybutyrate Test Strips
Container	Canisters
Storage	Store at 2-30°C Desiccant is contained on the walls of the canister to keep the Test Strips dry. To ensure the remaining Test Strips in the container are kept dry, reseal immediately after removing the needed Test Strips.
Stability	• **Unopened**: Stable until expiration date on the canister. • **Opened**: Test Strips must be used within 30 days.
Preparation	Each box of Test Strips contains a CODE Key containing electronic calibration information. Refer to section 8 for instructions to install the CODE Key on the meter.

Reagent	STAT - Site Diluent
Container	Manufacturer supplied vial
Storage	• Store unused vials at - 20°C or colder • Store opened/thawed vials at 2-8°C
Stability	• **Unopened**: stable until expiration date on the vial. • **Opened**: diluent is only stable for 30 days.
Preparation	Allow the frozen diluent to stand at room temperature until completely thawed. Swirl the contents gently to ensure homogeneity.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
STAT Site Controls (Low and High)	STANBIO Laboratories, Cat. No. 303000

6.2 Control Preparation and Storage

Control	STAT Site Controls (Low and High)
Preparation	Allow the frozen control to stand at room temperature until completely thawed. Swirl the contents gently to ensure homogeneity. Use immediately. After each use, promptly replace the stopper and return to 2 - 8° C storage.
Storage	• Store unused vials at - 20°C or colder • Stored opened/thawed vials at 2 - 8°C
Stability	• **Unopened**: stable until expiration date on the vial • **Opened**: stable for 30 days • Discard controls if turbidity or any change in appearance has occurred that may indicate contamination or deterioration.

6.3 Frequency

QC is to be done once per shift with patient testing. If a second test is ordered during the same shift, there is no need to rerun the QC. If no test is ordered during a shift, QC is not required to be run.

6.4 Tolerance Limits and Criteria for Acceptable QC

The control range is listed in Unity Real Time and on the Low and High Control vial labels.

QC is entered manually in Unity Real Time as follows:

1. Log into Unity Real Time
2. Select the appropriate Lab site
   a. GEC: 544235 GEC X-pand 1
   b. SGMC: 137244 SG Centaur
   c. WAH: 216442 WAH Centaur
3. Select STAT-Site Control, Level 1 or Level 2

If …	Then …
The QC result is out for the first time	• Refer to addendum 2 and clean the Test Strip Platform. • Verify that the test strips and controls are within expiry date. • Verify that the controls have been properly stored and are within open use life date. • Repeat QC
The QC result is out for the second time	Thaw fresh QC and repeat
The QC result is still out	Inform the Supervisor, Group Lead or Tech in charge. Contact Customer Service Support Center to troubleshoot. Do not result any patient testing until the QC trouble shooting is finished successfully.

Step	Action
1	Acceptable ranges for QC are programmed into the Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed

Step	Action
	according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of Test Strips or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples, when available. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

STAT-Site M$^{β-HB}$ Meter

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -50°C.
- Centrifuge

7.3 Supplies

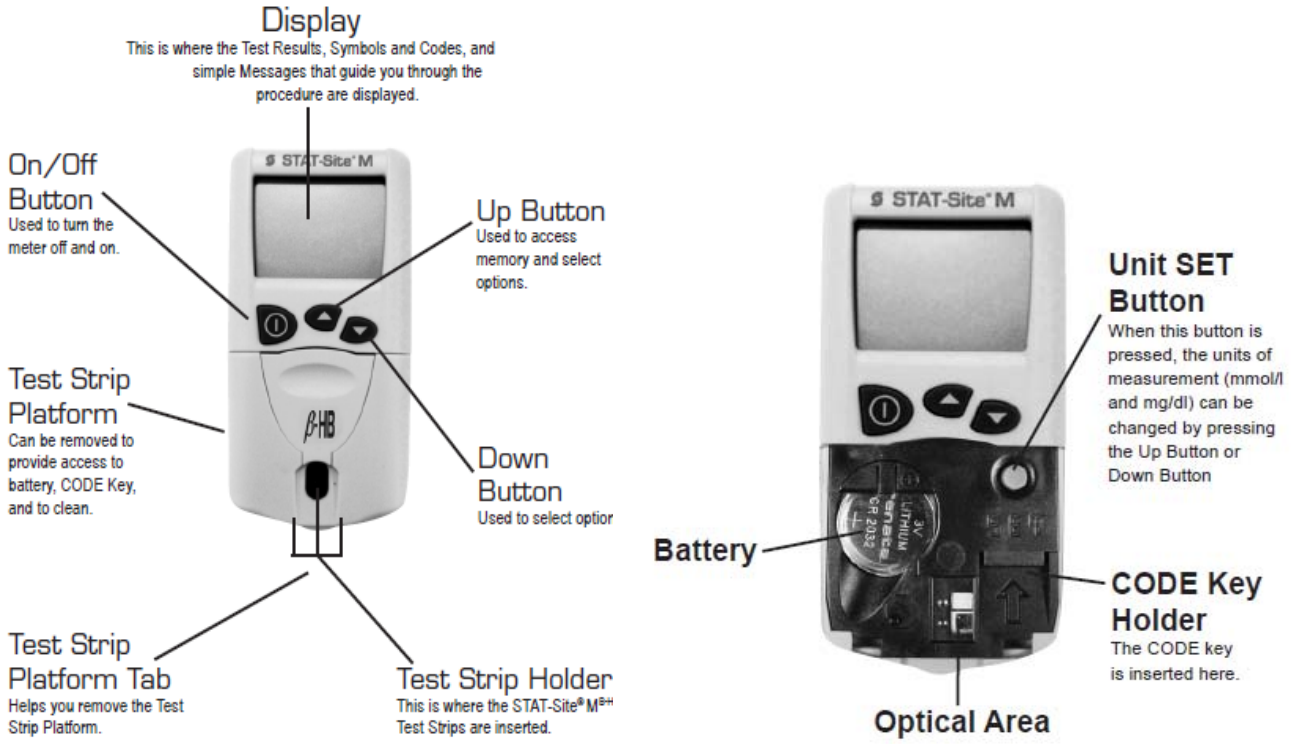
- Calibrated 10 µL pipette and disposable tips

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Code the Meter
1.	Turn the meter on.
2.	If No CODE or a CODE number different from the CODE of the Test Strip that you are using is displayed on the screen, remove the test strip platform (see picture below) by gently, but firmly, pushing up on the tab at the bottom of the test strip platform.
3.	Insert the appropriate CODE Key (included in the box of Test Strips) in the opening marked with an arrow.
4.	When the CODE Key has been correctly inserted, the meter will display "CODE," the coded TEST NAME (Ketone), and the CODE NUMBER.
5.	Replace the Test Strip Platform by lining up the top end of the test strip platform with the matching edge of the meter. Press down on the platform until it snaps firmly into place. **Note: If the platform is not fully reseated, test results will not be accurate.**
6.	The operator may leave the CODE Key in place and replace the test strip platform. **Notes:** • If multiple meters are in use, the key can be removed and used to code another meter. The CODE Key provides the standard curve for the lot of Test Strips. • The Test Strips and CODE Key are matched by lot number. The operator may leave the CODE Key in the meter but it should be discarded after the last Test Strip from the box is used. • If the wrong CODE Key is used, results will not be accurate.
7.	Turn the meter off.

8.2	Measurement Setting
1.	Remove the Test Strip Platform.
2.	Insert a CODE Key.
3.	Turn the meter on.
4.	Press and hold the blue SET button until "mmol/L" flashes.
5.	To change the unit of measure that is displayed, press either the UP or DOWN button.
6.	Turn the meter off and replace the test strip platform.



8.3	Performing the Test
1.	Turn on the meter by pressing the blue On/Off button on the left. **Note:** Check the Test Strip Platform to make sure it is clean and clear. Refer to Addendum 2 for description and images.
2.	Wait for the flashing Test Strip symbol to appear, and then insert the Test Strip.
3.	Slide the Test Strip, arrow side up and with arrows pointing toward the meter, into the slot provided (see Figure 1a). Continue until it stops (see Figure 1b). The Test Strip locks into place. To remove Test Strip, pull the Test Strip out of the meter.
4.	When the display shows the Test Type (Ketone), an unblinking Test Strip symbol, and a Flashing Drop symbol, it is time to apply the sample (see Figure 2).

8.3	Performing the Test
5.	Apply 10 µL sample onto the center of the pad of the Test Strip. Do NOT touch the pipette tip to the pad (see picture below).
6.	After applying the sample to the center of the Test Strip, the countdown to test result will begin at 80 seconds. Do not touch or reposition the Test Strip while meter is testing.

Figure 1a

Figure 1b

When you see an unblinking Test Strip symbol and a Flashing Drop symbol, apply the sample.

Figure 2

Pipette 10 µL of serum or plasma onto the pad on the test strip.

8.4	Dilution Procedure
1.	As the diluent is derived from human serum, there is β-hydroxybutyrate present. To account for this, the diluent must be run first; record value as Background (BG). **NOTE: Accurate pipetting in the dilution procedure is critical to obtaining accurate results.**
2.	Prepare a 1:2 dilution using the STAT-Site Diluent.
3.	Test the diluted sample; record the value as Diluted Analyte.
4.	Refer to section 9 for calculation.

9. CALCULATIONS

The instrument automatically calculates the concentration of Ketone (β – Hydroxybutyrate) in mmol/L.

Use the following formula when diluting samples: (2 x Diluted Analyte) - Background

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The STAT Site Meter provides a direct reading of ß - Hydroxybutyrate. Values below or above the test range will be reported as <Lo> or <Hi> on the display screen.

10.2 Rounding

No rounding is necessary. Instrument reports results with two decimal points.

10.3 Units of Measure

mmol/L

10.4 Clinically Reportable Range (CRR)

0.01 – 4.00 mmo/L

10.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions, such as an unusually high percentage of abnormal results.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall within the AMR or CRR may be reported without repeat.

IF the result is …	THEN…
Lo	Inspect the sample and make sure it does not have cellular debris and/or fibrin clots. Report as: < 0.01
Hi	Manually dilute the sample using dilution factor of 2 (equal volume of diluent and sample). **Diluent:** STAT Site Diluent **Refer to section 9 for dilution calculation**
Hi (after dilution)	If the recommended dilution does not give results within the clinically reportable range, report as: "> 4.00 mmol/L-REP" ~~Bring to the attention of your supervisor prior to releasing result.~~

Message	Code
Verified by repeat analysis	Append –REP to the result.

Form revised 2/02/2007

To enter patient results in the LIS, use function MEM
Enter Shift: (1, 2, or 3)
Worksheet: Use WCH1 for WAH, SCH1 for SGMC, or GCH1 for GEC
Test: <Enter>
Enter "A" (Accept)
Enter Accession number
Press <Enter> until Result screen is displayed
Input result

11. EXPECTED VALUES

11.1 Reference Ranges

0.02 – 0.27 mmol/L

11.2 Critical Values

None established

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

The detection of ketosis is important in several clinical conditions. The most important is the detection of potentially fatal keto-acidosis in diabetics. Patients with Type 1 diabetes are prone to developing ketoacidosis – an excessive buildup of ketones in the blood due to accelerated ketone synthesis and the body's limited capacity to break them down.
Measuring the level of ketones is clinically useful in not only diagnosing Diabetic Ketoacidosis (DKA), but also in monitoring the results of treatment. Diabetics should be tested for the presence of ketones when any symptoms of ketoacidosis are present, during acute illness or stress, when blood glucose levels consistently exceed 240 mg/dL and during pregnancy.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.01 – 2.00 mmol/L

14.2 Precision

Material	Mean mmol/L	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Low Control	0.46	0.03	5.9
High Control	1.5	0.07	4.4

14.3 Interfering Substances

No significant change in values was observed when the following compounds were added to serum containing 0.8 to 1.0 mmol/L β-Hydroxybutyrate as shown below. Glucose (2000 mg/dL), Creatinine (100 mg/dL), Uric Acid (100 mg/dL), Bilirubin (45 mg/dL), Lactic Acid (25 mg/dL), Ascorbic Acid (0.5 mg/dL), Aceacetate (2.0 mM/L), Hemolysis (2000 mg/dL), Lipemia (1000 mg/dL), and Salicylate (400 mg/dL)

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

Avoid skin contact with reactive areas of the strip.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Safety Data Sheets (SDS)
4. Quest Diagnostics Records Management Procedure
5. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
6. Hemolysis, Icteria and Lipemia Interference (Lab policy)
7. Repeat Testing Requirement (Lab policy)
8. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
9. Ketone (β – Hydroxybutyrate) Test Patient Log (AG.F349)
10. Ketone (β – Hydroxybutyrate) Test Maintenance Log (AG.F351)
11. Current package insert Ketone (β – Hydroxybutyrate) Test

17. REFERENCES

1. Package Insert, Ketone (β – Hydroxybutyrate) Test, STANBIO Laboratory, 01/2017
2. Package Insert, STAT Site Controls, STANBIO Laboratory, 05/2017
3. Package Insert, STAT Site Diluent, STANBIO Laboratory, 03/2014.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
0	5/11/18	Header	Add other sites	L Barrett	R SanLuis
0	5/11/18	4,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
0	5/11/18	6.6	Qualify use of patient samples for new lots testing	D Collier	R SanLuis
0	5/11/18	7.2	Change freezer range to match practice	L Barrett	R SanLuis
0	5/11/18	10.5	Review data moved from section 6	L Barrett	R SanLuis
0	5/11/18	10.6	Remove supervisor notification	D Collier	R SanLuis
0	5/11/18	15	Update to new standard wording, move hazard statement from section 4	L Barrett	R SanLuis
0	5/11/18	17	Update package insert dates	D Collier	R SanLuis
0	5/11/18	Add 2	Add lint-free cloth for cleaning	D Collier	R SanLuis

19. ADDENDA

1. Instrument Error Code Messages
2. Maintenance

Addendum 1

Instrument Error Code Messages

Error Code	Description
E – 1	**Temperature Error:** Room temperature outside of operating temperature.
E – 4	**Meter Error:** Clean meter and retest.
E – 5	**Strip Error:** Clean meter and retest with new Test Strip.
E – 6	**Calibration Error:** Call Technical Support
E – 8	**Code Key Error:** Turn meter off. Insert CODE Key. Turn meter on.

Addendum 2

Maintenance

It is important that the meter is kept clean. The following maintenance steps are recommended:

1. The Outside Case - The outside plastic case of the STAT Site Meter, including the Test Strip Platform, can be cleaned with cotton swabs or gauze. The Test Strip Platform may be removed to clean separately. Be careful not to scratch the Test Strip Platform window.
2. The Display Screen and Optical Areas - To clean the display screen, the glass window optical areas of the test strip platform, and the optical detector window use gauze or lint-free cloth moistened with water. Be careful not to scratch the window.

Notes:

- Keep the STAT Site Meter dry and do not expose to extremes of temperature or humidity.
- Do not expose the buttons, LED Display area or optical glass area to excessive liquids as damage to electronic components may occur.
- The meter will warn the operator when the battery is getting low by displaying a battery symbol (see picture below). From the time the battery symbol first appears you have enough power to perform a minimum of 10 tests. The test results will be accurate, but the battery should be changed. If there is not enough power to produce an accurate result, the meter will shut off during testing or not power on.