COLLEGE of AMERICAN PATHOLOGISTS

HCC2-B 2017

Kit Instructions

Waived Combination Survey

Kit Contents

Three whole blood specimens

- WB-07 — WB-09

For replacement materials, contact the CAP immediately.

Important: Before You Begin

New for this Mailing

None

Reporting Code Changes

The following manufacturers have either deleted or updated codes for this mailing:

None

Storage and Stability Instructions

1. Upon receipt, store specimens upright at 15 - 30°C until testing can be performed. **Do not freeze.**
2. Once open, vials are stable for 30 days at 15 - 30°C.

Critical Reporting Information

1. For any testing that you do not routinely perform in your laboratory, leave all reporting areas for that test blank unless otherwise noted.
2. The result form is available in an HTML format via e-LAB Solutions Suite. Depending on the program's reporting requirements, sections of the result form may include logic that flags missing required information (eg, units of measure, methods). Your laboratory must still verify and approve **all** data prior to the due date.

Detailed Testing Instructions

Handling Instructions

1. Specimens must be at room temperature prior to analysis.
2. **It is imperative that specimens are mixed well. Do not mix mechanically; do not vortex.**
   a. Hold each vial horizontally between the palms of the hands and roll each vial back and forth for 20 - 30 seconds.

ANAB ACCREDITED ISO/IEC 17043 PROFICIENCY TESTING PROVIDER

Important: See the Biohazard Warning at the end of these instructions.

ATTACHMENT D

Per CLIA, as published by the United States Federal Register

- Proficiency Testing (PT) specimens must be tested with the laboratory's regular workload, using routine methods, and testing the PT specimens the same number of times it routinely tests patient specimens.
- If referral for testing is routinely performed for patient specimens, the practice cannot be followed for PT specimens. Referral is considered to be movement of the specimen from a laboratory with a CLIA identification number to another laboratory that has a different CLIA identification number.
- Laboratories must ensure that personnel do not share results or refer PT specimens for any reflex or testing outside their CLIA identification number.

Disclaimer

Survey specimens, their progeny, unmodified derivatives, or modifications thereof may not be transferred or incorporated into a program intended for sale. Survey specimens, their progeny, unmodified derivatives, or modifications thereof, reagents, and disposable equipment used in PT, when disposed of, should be autoclaved or incinerated and disposed of as hazardous waste. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

   b. Continue to mix by rapid inversion until the red blood cells are completely resuspended and each specimen is homogeneous. If the red blood cells are left on the bottom of the vial, values will be affected.
   c. Gently invert the vials 8 - 10 times immediately before sampling.
3. Apply the specimen as described by the instrument manufacturer's instructions for patient specimens. Do **not** permit the dropper tip to come in direct contact with the reagent strip pad or draw any portion of the specimen back into the vial.
4. Wipe the dropper tip and threads of the vial with a clean tissue prior to tightly replacing the cap.
5. **Abbott FreeStyle Precision Pro users:** Analyze Proficiency Survey material in the Proficiency Test mode only.

Reporting Your Results

General Reporting Instructions

1. Each mailing, verify the accuracy of your reporting codes (eg, manufacturer, method, instrument, reagent) by reviewing the online result form or the Method Summary Page attached to the front of your result form.
2. **Exception Codes:** If you must report an analytical problem for a test or individual analyte, **leave the result area for that section blank** and select one of the following bubbles on the result form within that section. The exception code bubble that you select will apply **only** to the result area(s) left blank. Documentation on the use of these codes is the responsibility of the laboratory and should be kept internally.
   - **11 Unable to analyze**
     Use code 11 to indicate why specimens were not analyzed (eg, instrument not functioning, reagents not available).
   - **22 Result is outside the method/instrument reportable range**
     Use code 22 if you obtain a high or low result outside the reportable range of your method or instrument. Do not use this code if there is an option to select **greater than** or **less than**.
   - **33 Specimen unsatisfactory**
     To use code 33, you **must** contact the CAP.

   If you select an exception code bubble **and** enter data on the result form, the data will be graded.
3. Quantitative results for this Survey can now be automatically transmitted using e-LAB Solutions Connect. To learn more, visit cap.org and search for e-LAB Solutions Connect.

Submitting Results

1. Results **must** be received at the CAP no later than midnight, Central Time by the due date on the result form.
2. Your site administrator must establish a Web account via cap.org and opt in your laboratory. Information about opting in and a unique PIN was emailed to all laboratory directors. If your laboratory director does not have this information, contact the CAP.
3. Laboratory staff who enter results online must first create a personal Web account, affiliate themself with a laboratory, then log in.

Biohazard Warning

All Survey specimens should be treated as if potentially infectious and should be handled as if they are capable of transmitting disease.

Survey specimens are prepared from blood or other source material obtained from human donors or animals.

When working with Survey specimens, precautions should be taken to protect yourself and others from accidental exposure to infectious agents such as HIV, HBV, and HCV.

HIV can be transmitted through accidental parenteral inoculation, mucous membranes, or non-intact skin contact with HIV infected blood or body fluids. HBV and HCV can be transmitted through accidental parenteral inoculation, mucous membranes, non-intact skin contact, aerosolization or ingestion.

Precautions described in CDC and FDA recommendations and OSHA blood borne pathogen rules should be followed at all times when handling Survey specimens and reagents.

Such precautions include the following:

- Gloves should be put on **before opening the container** and should be kept on throughout the period specimens are handled. Replace gloves if contaminated, or if their ability to function as a barrier is compromised.
- At high altitudes, specimens should be opened in a hood or biologic safety cabinet.
- There should be no eating, drinking, or smoking in the laboratory.
- Hands should be washed after removing gloves and before leaving the testing area.
- Survey specimens and reagents should be kept in separate refrigerators from those containing blood or blood components for transfusion.
- Survey specimens, reagents, and disposable equipment used in testing should be autoclaved or incinerated and disposed of as hazardous waste. Disposal must follow local regulations, if more stringent than regulations enforced by the CDC or the FDA.

Warning: This Survey may contain a chemical known to the State of California to cause cancer.

If there has been an accident in which you have been exposed to the Survey's materials, please call the CAP Hot Line at 800-443-3244 (domestic) or 001-847-470-2812 (international) at any time. You can access Safety Data Sheets (SDS/MSDS) by logging on to cap.org, clicking on the Laboratory Improvement tab, then Catalog and Ordering Information.

For Assistance

Provide your CAP number and contact information with all correspondence. Participants in countries serviced by a designated CAP distributor should contact their distributor's customer service department.

Telephone: 800-323-4040 option 1
(Monday - Friday, 7:00 AM – 5:30 PM US Central Time)
International Participants: 001-847-832-7000 option 1

Email: contactcenter@cap.org
Website: cap.org

Address: CAP Surveys Program
325 Waukegan Road
Northfield, IL 60093-2750
USA

Instrument Master List

Deleted codes
None

New/Updated codes
None

1082	Abbott FreeStyle Precision H	1777	Bionime Rightest GM700	1241	Nipro TRUEresult
1087	Abbott FreeStyle Precision Pro	1878	Bionime Rightest GM700 Pro	1249	Nipro TRUEtrack
1221	Abbott Precision Xceed Pro	2573	BTNX Rapid Response	2184	Nova StatStrip
1610	Abbott Precision Xtra	1209	Clarity Plus	1976	Roche Accu-Chek Active
3326	Assure Platinum	3439	Glucocard Expression	2087	~~Roche Accu-Chek Aviva~~
3438	Assure Prism	3440	Glucocard Vital	3431	Roche Accu-Chek Inform II
1794	Bayer Ascensia Contour 7151A (15 sec)	2093	LifeScan SureStep/Pro/Flexx code 1-9 (001-009)	3432	Roche Accu-Chek Performa
1798	Bayer Ascensia Contour 7151B (5 or 8 sec)	1072	LifeScan SureStep/Pro/Flexx code 10-15 (010-015)	0010	Other, specify on result form
1136	Bayer Ascensia Elite, Elite XL				

Inclusion on this master list does not imply US FDA approval.

HCC2-B

2017

Last Updated:

KIT 30587614 3 01 50

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CAP # 8657256 - 01 SEQ # 01
Products:HCC2
Venango County VA OPC
Joanne Camp
TEL# 1-866-962-3210 ext. 6620 FAX# 1-814-437-9020

Results must be received at the CAP no later than midnight, Central Time by the due date below:

July 11, 2017

Online: cap.org (preferred method)

Fax: 866-FAX-2CAP (866-329-2227)

Waived Combination Survey Result Form

Important

To print results, you must first save your data.

Results cannot be accepted if received after the due date.

Corrections can be made to this result form at any time **prior** to the due date. For results that are approved online, corrections must also be done online. Faxed or mailed corrections will not be accepted.

If you submit results online, you must click **APPROVE AND SUBMIT TO CAP** in order for results to be received at the CAP.

Whole Blood Glucose Results

010 Instrument Code: 3431

020 Unit of Measure: ● 101 mg/dL ○ 107 mmol/L

030 Exception Code: ○ 11 ○ 22 ○ 33

WB-07	WB-08	WB-09
040	050	060

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Last Updated:

KIT 30587614 3 02 93

CAP # 8657256 - 01 SEQ # 01

Products:HCC2

Venango County VA OPC

Joanne Camp

TEL# 1-866-962-3210 ext. 6620 FAX# 1-814-437-9020

July 11, 2017

Attestation/Use of Other Form

Attestation Statement

As stated in the February 28, 1992 United States *Federal Register* under Subpart H 493-801 (b) (1), the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods. The laboratory director or designee and the testing personnel must sign on the result form. Retain a signed copy of this page in your laboratory for your records and inspection purposes. Attestation is a requirement for all CAP-accredited laboratories.

If your laboratory requires additional space for signatures, copy this form as needed.

We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number.

Director (or Designee) (signature required)

010

Survey Mailing Information (eg, CA2017)

030

Testing Personnel (signature required)

040

Testing Personnel (signature required)

070

Testing Personnel (signature required)

100

Use of Other

This section is provided to list methodology information not found on master lists. For online entry, you can enter only 255 characters.

CAP Accreditation Program Participants: Do not use this section to make changes to your Test/Activity Menu. You can access a Test/Activity Menu Change Form through e-LAB Solutions Suite.

130

Signatures will not display when viewed online.

Customer Contact Center 800-323-4040 option 1 (domestic)
or 001-847-832-7000 option 1 (international)

AO

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