COLLEGE of AMERICAN PATHOLOGISTS

HCC2-A 2017

Kit Instructions

Waived Combination Survey

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Kit Contents

Two whole blood specimens
- HE-01 and HE-02

Two urine specimens
- CM-01 and CM-02

Important: Before You Begin

New for this Mailing

Beginning with this mailing, 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.

Reporting Code Changes

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

- Arkray

Storage and Stability Instructions

1. Upon receipt store specimens at 2 - 8°C.
2. Specimens are stable for 14 days at this temperature.

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. A unit of measure (UOM) must be filled in for the hemoglobin (HGB) challenge for proper evaluation.
3. If you report hematocrit (HCT) using microhematocrit centrifugation, spin these specimens for exactly 5 minutes. This instruction does **not** apply to CritSpin/StatSpin or HemataSTAT II/C-70 users
4. **Urinalysis: Failure to select an inappropriate instrument, method, or manufacturer may result in comparison with the wrong peer group and unacceptable performance.** To accommodate various reporting styles, multiple reporting sections are provided for protein, glucose, ketones, bilirubin, blood/hemoglobin, and leukocyte esterase. **Choose ONLY 1 reporting method to enter your results.** Report results as you would a patient result.
   - If you use the Siemens Reagent Strip on the Siemens Clinitek 500, report your

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ATTACHMENT C

method as 2936 Siemens Reagent Strips (All) and your instrument as 2292 Siemens Clinitek 500.

- If you use the Roche Chemstrip and read this visually, report your method as 2937 Roche Chemstrip/combur and your instrument as 2044 Visual.

Detailed Testing Instructions

Handling Instructions

Whole blood specimens for hemoglobin and hematocrit testing:

1. Allow the vial to stand at room temperature for 20 minutes before mixing.
2. Briskly roll the vial back and forth between the palms of the hands for 60 seconds, then gently invert 10 times.
3. Mix until the cells are completely and uniformly suspended, ie, no cell button is seen on the bottom of the tube. Do not shake the vial or use a mechanical mixer.
4. Allow the vial to rest undisturbed about 15 seconds for dispersion of small air bubbles.
5. Immediately prior to use, gently invert the vial 10 times.
6. **Hemocytometer Users:** Preparation time must be extended to ensure proper lysing of fixed cells. The initial dilution should sit for 20 - 30 minutes in the Unopette. During this time period, prepare a Petri dish moisture chamber by moistening a folded paper towel or other absorbent material with water and placing it in the bottom of the Petri dish. The hemocytometer should be placed on top of the moist towel and allowed to sit in the covered moisture chamber for 10 - 15 minutes before reading. The moist chamber will prevent specimen evaporation.

Urine specimen testing:

Urinalysis

1. Allow specimen to come to room temperature for 20 minutes before mixing.
2. Mix specimen well before beginning tests. **Complete testing within 8 hours.** Perform only those tests that are ordinarily performed in your laboratory.
3. Do not perform confirmatory tests for positive dipstick results, even though your laboratory protocol requires them for patient specimens.
4. The analyte used in urine proficiency specimens for bilirubin and urobilinogen testing may give slightly atypical (pink) color development by some methods when examined visually. If this occurs, the specimen should be graded based upon the intensity of the color.

Urine hCG

1. Allow specimen to come to room temperature before mixing.
2. Mix specimen well before beginning tests.
3. **Complete testing within 8 hours.**

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. The inclusion of reporting codes on the result form does not imply US FDA approval.
3. **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.

4. An option for **greater than** values is provided in certain sections of the result form. Select the option if appropriate and enter your highest detectable limit in the boxes provided or refer to the use of exception codes.
5. 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.
6. For reporting Urinalysis and Specific Gravity method and instrument codes, refer to list below for examples:

If you use:	Then for method use:	Then for instrument use:
Refractometer	2533 Refractometer	2044 Visual
Siemens Reagent Strip on Siemens Clinitek 500	2936 Siemens Reagent Strip	2292 Siemens Clinitek 500
Siemens Reagent Strip and read visually	2936 Siemens Reagent Strip	2044 Visual
Roche Chemstrip on Roche Chemstrip 101	2937 Roche Chemstrip	3241 Roche Chemstrip 101
Roche Chemstrip and read visually	2937 Roche Chemstrip	2044 Visual

7. **Bayer Acetest users:** Results should be read at 30 seconds as instructed for urine specimens in the Bayer package insert. Positive results may change if incubated longer due to the use of surrogate material for the Ketone analyte.
8. **Reducing Substances:** If your laboratory performs reducing substances, you must perform both challenges, otherwise leave blank if your laboratory does not perform this test.
9. **Urobilinogen:** If you select the reporting bubble for code **418,** note that < 35 µmol/L is to be used by ARKRAY Aution MAX users only.
10. **Roche users:**
    - **Chemstrip, Specific Gravity (Visual):** For increased accuracy, add 0.005 to the reading if the pH is ≥ 7.0. (If the strip is read on an instrument, the correction is applied automatically.)
    - **pH:**
      - **pH Visual:** Results should be reported in whole numbers; 0.5 increments are not allowed.
      - **Cassette and all other pH Instrumentation:** Results should be reported in whole numbers from 5.0 to 9.0, with the exception of 6.5.
    - **Glucose:**
      - **Roche Glucose Visual Method only:** Results may be reported as 500 mg/dL.

- **All Other Roche Glucose Methods:** 500 mg/dL is not an appropriate response. Analyzers are not able to discern results of 500 vs. 1000 mg/dL.
- **Ketones:** All Roche Urinalysis instruments should not report 80 - 100 mg/dL. Analyzers are not able to discern ketones between 60 and 150.
- **Protein, Urisys 1100:** 75 mg/dL is not an appropriate response.

11. **Siemens users:**
    - **Multistix, Specific Gravity (Visual):** According to the Siemens package insert, for increased accuracy add 0.005 to the visual specific gravity reading when the urine pH is equal to or greater than 6.5. Report the corrected specific gravity on your result form. (Results from strips read by Clinitek are automatically corrected.)
    - **Clinitek Atlas users, Protein:** For reporting qualitative protein values of ≥ 300, select the bubble for 300 - 600 mg/dL or 3+.
12. When reporting a high qualitative value, **do not** choose a response greater than your method allows.

Conversion Table (Protein, Glucose, and Ketones)

Protein Method 2 reporting options in SI units	
Conventional (mg/dL)	SI (g/L)
Negative	Negative
10 - 20	0.1 - 0.2
30 - 70	0.3 - 0.7
75 - Roche Users only	0.75
100 - 200	1.0 - 2.0
300 - 600	3.0 - 6.0
> 600 or ≥ 1000	> 6.0 or ≥ 1000
Glucose Method 2 reporting options in SI units	
Conventional (mg/dL)	SI (mmol/L)
Negative	Negative
30 - 100	1.6 - 6.0
150 - 300	8.3 - 16.6
500	28
> 500 or ≥ 1000 or ≥ 2000	> 28 or ≥ 55 or ≥ 111
Ketones Method 3 reporting options in SI units	
Conventional (mg/dL)	SI mmol/L
Negative	Negative
5 -10	0.5 - 1.0
15 - 20	1.5 - 2.0
40 - 60	3.9 - 6.0
80 - 100	7.8 - 10.0
≥ 150	≥ 15.0

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.

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 mailing may contain chemicals known to the State of California to cause cancer, and to cause birth defects or other reproductive harm.

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

For replacement materials, please contact the CAP within **10** calendar days of the ship date for information. **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

Hematology Instrument Master List

Deleted codes
None

New/Updated codes
None

1939	Alere/Stanbio HemoPoint H2
1208	Clarity HbCheck
1523	Clay Adams Accu-stat
1393	Clay Adams Readacrit
1392	Clay Adams Triac
1272	Critspin/Statspin (glass tubes)
1273	Critspin/Statspin (plastic tubes)
2020	HemoCue B-Hb Analyzer
1990	HemoCue Hb 201+ Systems
3435	HemoCue Hb 301 Systems
1410	Microhematocrit (all PCV)
1745	STI HemataSTAT Easy Read
2030	STI HemataSTAT II/C-70
3430	STI UltraCrit
0010	Other, specify on result form

Urinalysis and Specific Gravity Method Master List

Deleted codes
~~3238 DiaScreen Reagent Strips~~

New/Updated codes
None

1733	77 Elektronika Reagent Strips
3367	ACON Mission Reagent Strips
1534	ARKRAY Aution Sticks
2547	Bayer Acetest
2544	Bayer Clinitest, 2 drop
2543	Bayer Clinitest, 5 drop
2922	Biorex DIAZO-CHEK
1798	Biorex K-Check
1626	BioSys/Consult Diag/PSS Select/YD Diag Reagent Strips
2574	BTNX Rapid Response Reagent Strips
1030	CTMI/Germaine Labs/Thermo Fisher Reagent Strips
3425	Diagnostic Test Group Clarity Urocheck Reagent Strips
1238	Eiken Uropaper
2831	IRIS vChem Reagent Strips
1114	Jant Accustrip URS 10 Reagent Strips
1381	Jant Accutest URS 10 Reagent Strips
3422	McKesson/Teco Reagent Strips
2468	Medline Urinalysis Reagent Strips
1095	M-N (Macherey-Nagel) Medi-Test Uryxxon test strips
2546	pH Meter
2533	Refractometer
3071	Roche Chemstrip LN
2937	Roche Chemstrip/Combur
2492	Roche cobas u Pack Cassette
1221	Roche Urisys Cassette
1313	Schein Urispec
2673	Siemens Clinitek Atlas Reagent
1622	Siemens Clinitek Novus/Pro Cassette
2538	Siemens Ictotest
2936	Siemens Reagent Strips (All)
3427	SMC Direct RefuAH Reagent Strips
1285	Sulfosalicylic acid
2552	Sysmex Reagent Strips
2534	Urinometer
0010	Other, specify on result form

Urinalysis and Specific Gravity Instrument Master List

Deleted codes
~~1106 DiaScreen 50~~

New/Updated codes
None

1935	77 Elektronika urine chemistry analyzers
3368	ACON Mission U120, U500
2126	ARKRAY Aution Hybrid
2675	ARKRAY Aution JET
2676	ARKRAY Aution MAX
1509	ARKRAY/Thermo BioStar Pock etChem UA
3444	BioSys/Consult Diag/PSS Select/YD Diag Urine Analyzer
2573	BTNX Rapid Response series
3424	Diagnostic Test Group Clarity Uro-check 120
3371	Eiken US-2100R/2200
3372	Eiken US-3100R/3100Rplus
1062	Germaine Labs AimStrip/CTMI CT-120 Urine Analyzer
1864	Germaine Labs AimStrip Urine Auto Analyzer
1689	Jant Accustrip URS 10 Reader
1096	M-N (Macherey-Nagel) Uryxxon series
3423	McKesson 107-101 UA
3241	Roche Chemstrip 101
1945	Roche Chemstrip Criterion, Criterion II
2097	Roche Chemstrip Urine Analyzer
1171	Roche Chemstrip Mini UA
1790	Roche cobas u411, Urisys 1800
2490	Roche cobas u601
1789	Roche Urisys 1100
1821	Roche Urisys 2400
1579	Siemens Clinitek 10 or 100
1845	Siemens Clinitek 50
1580	Siemens Clinitek 200 or 200+
2292	Siemens Clinitek 500, Advantus
1578	Siemens Clinitek 2000
1465	Siemens Clinitek Atlas
2681	Siemens Clinitek Novus
2532	Siemens Clinitek Status
3426	SMC Direct RefuAH U120
2186	Sysmex UX-2000
2603	Teco Uritek TC-101
2044	Visual
0010	Other, specify on result form

Urine hCG Manufacturer Master List

Deleted codes
None

New/Updated codes
None

1735	Abbott TestPack Combo
2027	Abbott TestPack Plus Combo w/ or w/out OBC
1736	Abbott TestPack Plus - Urine
1784	ABI SureStep
1782	ABI SureStep Combo
2938	Acceava Basic II (urine)
3168	Acceava Combo II
2648	ACON One Step (urine only)
2055	Alere hCG Cassette (20) (Acceava)
1959	Alere hCG Cassette (25) (Clearview)
2403	Alere hCG Combo Cassette (20/10)
1299	Alere hCG Combo Cassette (25) (Clearview)
2404	Alere hCG Dipstick
1161	Beckman Coulter ICON 20
2618	Beckman Coulter ICON 25
2010	BioTron Diagnostics Foremost Combo
2354	Cardinal Health SP Brand Cassette
2355	Cardinal Health SP Brand Combo
2356	Cardinal Health SP Brand Dipstick
2647	Cen-Med Elite Plus One Step hCG
2812	Clarity Test Cassette
2813	Clarity Test Strip
2120	Chembio STAT-PAK
1961	Clearview hCG Combo II
1430	Consult Diagnostics Cassette
1432	Consult Diagnostics Combo
1433	Consult Diagnostics Dipstick
1006	DE Healthcare Products TruView Cassette
3140	DE Healthcare Products TruView One-Step
3517	Ekla Novaplus hCG Combo
3516	Ekla Novaplus hCG urine
2860	Formosa One Sure Pregnancy Kit
1586	Germaine Labs AimStep
1587	Germaine Labs AimStep Combo
1679	Germaine Labs AimStrip
1205	Henry Schein OneStep+ Combo
1382	Henry Schein OneStep+ Urine Cassette
1383	Henry Schein OneStep+ Urine Strip
1117	Immunostics Immuno hCG Detector
1118	Immunostics Immuno hCG Detector Combi (serum/urine)
1119	Immunostics Immuno hCG Detector Stix
2474	Instant Technologies iPregnancy Cassette (serum/urine)
2475	Instant Technologies iPregnancy Cassette (urine only)
2476	Instant Technologies iPregnancy Strip (urine only)
1370	Jant Accustrip Value+
3409	Jant Accutest Value+ (serum/urine)
3410	Jant Accutest Value+ (urine only)
2981	LifeSign Status (serum/urine)
2980	LifeSign Status (urine only)
1180	LSC (LABSCO) PEP hCG Strip
1178	LSC (LABSCO) PEP hCG Test
1060	Mainline Confirms (combo)
1468	Mainline Confirms (urine only)
1477	McKesson Medi-Lab Performance Cassette
1478	McKesson Medi-Lab Performance Combo
1476	McKesson Medi-Lab Performance Dipstick
2276	MediChoice Combi
2277	MediChoice Urine Only
1091	Medline hCG Combo Cassette
2465	Medline hCG Urine Cassette
2466	Medline hCG Urine Dipstick
3209	Meridian ImmunoCard STAT
1491	NDC Pro Advantage Urine Cassette
1288	NDC Pro Advantage Urine/Serum Cassette
1492	NDC Pro Advantage Urine Strip
3061	Polymedco Poly stat (serum/urine)
2872	Polymedco Poly stat (urine only)
1372	Pulse Scientific
1414	Quidel QuickVue+One-Step Combo
1475	Quidel QuickVue One-Step Combo
1129	Quidel QuickVue One-Step Urine
1338	Quidel RapidVue (urine only)
2479	Ramco Quik-Trak (urine only)
2480	Ramco Quik-Trak Combi Test (serum/urine)
3137	Randox Direct
1800	Roche AccuStat Combo
2108	SA Scientific (serum/urine)
2107	SA Scientific (urine only)
2483	SA Scientific (SAS) Ultra
1836	Sekisui OSOM
1837	Sekisui OSOM Combo
1270	Sekisui OSOM Ultra Combo
2532	Siemens Clinitek Status
2853	Signify hCG Card
2854	Signify hCG Urine
2855	Signify hCG Urine/Serum
2442	SMC Direct RefuAH Combo
2441	SMC Direct RefuAH Urine
1438	Stanbio QuPID
1439	Stanbio QuPID Plus
3425	Stanbio QuPID Plus E.R.
1135	Stanbio QuStick
3424	Stanbio True 20 Plus
1467	Sure-Vue (serum/urine)
1466	Sure-Vue (urine only)
2052	Sure-Vue STAT (serum/urine)
3428	Technologist Choice (serum/urine)
1844	Trinity Biotech UniGold PT
2559	Wampole UCG-Slide Test
3158	Wondfo One Step hCG Urine
3159	Wondfo One Step hCG Urine/Serum
0010	Other, specify on result form

CAP

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2017

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

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.

HGB

010 Instrument Code

020 Unit of Measure ○ 112 g/dL ○ 141 g/L

030 Exception Code ○ 11 ○ 22 ○ 33

HE-01
040 ___ . ___

HE-02
050 ___ . ___

HCT

060 Instrument Code

070 Unit of Measure ○ 126 % ○ 152 L/L

080 Exception Code ○ 11 ○ 22 ○ 33

HE-01
090 ___ . ___

HE-02
100 ___ . ___

16318

APN1

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

Specific Gravity

Alert! When reporting a high quantitative value, do not choose a response greater than your method allows.

010 Method Code

020 Instrument Code

030 ○ 11 ○ 33 Exception Code

CM-01

040 ____ . ____

050 ○ (4) Fill if less than
○ (5) Fill if greater than

CM-02

060 ____ . ____

070 ○ (4) Fill if less than
○ (5) Fill if greater than

pH

Alert! Roche pH Visual users: Results should be reported in whole numbers; 0.5 increments are not allowed.
Alert! Roche Cassette and all other Roche pH users: Results should be reported in whole numbers from 5.0 to 9.0 with the exception of 6.5.

080 Method Code

090 Instrument Code

100 ○ 11 ○ 33 Exception Code

CM-01

110
○ 130 ≤3.5
○ 131 4.0
○ 132 4.5
○ 133 5.0
○ 134 5.5
○ 135 6.0
○ 136 6.5
○ 137 7.0
○ 138 7.5
○ 144 8.0
○ 177 8.5
○ 145 ≥9.0

CM-02

120
○ 130 ≤3.5
○ 131 4.0
○ 132 4.5
○ 133 5.0
○ 134 5.5
○ 135 6.0
○ 136 6.5
○ 137 7.0
○ 138 7.5
○ 144 8.0
○ 177 8.5
○ 145 ≥9.0

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

Protein

Alert! When reporting a high quantitative value, do not choose a response greater than your method allows.

Alert! Clinitek Atlas users: For Protein values of ≥ 300, including values of 600 or ≥ 1000 mg/dL, select the bubble for 300 - 600 mg/dL or 3+.

Reporting Method 1

010 Method Code ☐☐☐☐ 020 Instrument Code ☐☐☐☐ 030 ○ 11 Exception Code ○ 33

CM-01		CM-02	
040 ○ 110 Negative	○ 207 (2+)	050 ○ 110 Negative	○ 207 (2+)
○ 533 Trace	○ 206 (3+)	○ 533 Trace	○ 206 (3+)
○ 208 (1+)	○ 205 (4+)	○ 208 (1+)	○ 205 (4+)

Reporting Method 2 (Unit of Measure – mg/dL)

Alert! See conversion table on the kit instructions for information about equivalent conventional and SI values.

060 Method Code ☐☐☐☐ 070 Instrument Code ☐☐☐☐ 080 ○ 11 Exception Code ○ 33

CM-01		CM-02	
090 ○ 110 Negative	○ 257 100 - 200	100 ○ 110 Negative	○ 257 100 - 200
○ 256 10 - 20	○ 258 300 - 600**	○ 256 10 - 20	○ 258 300 - 600**
○ 255 30 - 70	○ 259 > 600 or ≥ 1000	○ 255 30 - 70	○ 259 > 600 or ≥ 1000
○ 109 75 - Roche users only*		○ 109 75 - Roche users only*	

* Not appropriate for Roche Urisys 1100 users.

** **Clinitek Atlas Users:** report ≥ 300 mg/dL, including values of 600 or ≥ 1000 mg/dL, as 300 - 600 mg/dL.

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

Glucose

Alert! Select only one reporting method. Do not select more than one reporting area.

Reporting Method 1

Method Code 010 [ ] Instrument Code 020 [ ] Exception Code 030 ○ 11 ○ 33

CM-01		CM-02	
040 ○ 110 Negative	○ 207 (2+)	050 ○ 110 Negative	○ 207 (2+)
○ 533 Trace	○ 206 (3+)	○ 533 Trace	○ 206 (3+)
○ 208 (1+)	○ 205 (4+)	○ 208 (1+)	○ 205 (4+)

Reporting Method 2 (Unit of Measure = mg/dL)

Alert! See conversion table on the kit instructions for information about equivalent conventional and SI values.

Method Code 060 [ ] Instrument Code 070 [ ] Exception Code 080 ○ 11 ○ 33

CM-01	CM-02
090 ○ 110 Negative	100 ○ 110 Negative
○ 260 30 - 100	○ 260 30 - 100
○ 296 150 - 300	○ 296 150 - 300
○ 297 500*	○ 297 500*
○ 261 > 500 or ≥ 1000 or ≥ 2000	○ 261 > 500 or ≥ 1000 or ≥ 2000

***Roche Glucose Visual Method:** Results may be reported as 500 mg/dL.
All Other Roche Glucose Methods: Should **not** report 500 mg/dL. Analyzers are not able to discern results of 500 vs. 1000 mg/dL.

Reducing Substance

Alert! If your laboratory performs reducing substances, you **must** perform **2** challenges, otherwise leave blank if your laboratory does not perform this test.

Method Code 110 [ ] Exception Code 120 ○ 11 ○ 33

CM-01		CM-02	
130 ○ 120 Negative	○ 215 3/4%**	140 ○ 120 Negative	○ 215 3/4%**
○ 124 1/4% (trace)	○ 218 1%	○ 124 1/4% (trace)	○ 218 1%
○ 212 1/2%	○ 221 ≥ 2%	○ 212 1/2%	○ 221 ≥ 2%

** Please note 3/4% is not an appropriate response for the Bayer Clinitest, 2-drop method.

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

Ketones

Alert! Select only one reporting method. Do not select more than one reporting area.

Reporting Method 1

010 Method Code ☐☐☐ 020 Instrument Code ☐☐☐☐ 030 Exception Code ○ 11 ○ 33

CM-01

040
- ○ 120 Negative
- ○ 533 Trace
- ○ 365 Small
- ○ 366 Moderate
- ○ 367 Large

CM-02

050
- ○ 120 Negative
- ○ 533 Trace
- ○ 365 Small
- ○ 366 Moderate
- ○ 367 Large

Reporting Method 2

060 Method Code ☐☐☐ 070 Instrument Code ☐☐☐☐ 080 Exception Code ○ 11 ○ 33

CM-01

090
- ○ 110 Negative
- ○ 533 Trace
- ○ 208 (1+)
- ○ 207 (2+)
- ○ 206 (3+)
- ○ 205 (4+)

CM-02

100
- ○ 110 Negative
- ○ 533 Trace
- ○ 208 (1+)
- ○ 207 (2+)
- ○ 206 (3+)
- ○ 205 (4+)

Reporting Method 3 (Unit of Measure = mg/dL)

Alert! See conversion table on the kit instructions for information about equivalent conventional and SI values.

110 Method Code ☐☐☐ 120 Instrument Code ☐☐☐☐ 130 Exception Code ○ 11 ○ 33

CM-01

140
- ○ 110 Negative
- ○ 348 5 - 10
- ○ 347 15 - 25
- ○ 349 40 - 60
- ○ 350 80 - 100*
- ○ 351 ≥ 150

CM-02

150
- ○ 110 Negative
- ○ 348 5 - 10
- ○ 347 15 - 25
- ○ 349 40 - 60
- ○ 350 80 - 100*
- ○ 351 ≥ 150

* Roche Urinalysis instruments should not report 80 - 100 mg/dL. Analyzers are not able to discern ketones between 60 and 150.

HCC2-A
2017

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

Bilirubin*

Alert! Select only one reporting method. Do not select more than one reporting area.

Reporting Method 1

Method Code 010 ☐☐☐☐ Instrument Code 020 ☐☐☐☐ Exception Code 030 ○ 11 ○ 33

CM-01

040 ○ 120 Negative
○ 369 Trace/Small
○ 368 Positive/Moderate
○ 367 Large

CM-02

050 ○ 120 Negative
○ 369 Trace/Small
○ 368 Positive/Moderate
○ 367 Large

Reporting Method 2

Method Code 060 ☐☐☐☐ Instrument Code 070 ☐☐☐☐ Exception Code 080 ○ 11 ○ 33

CM-01

090 ○ 110 Negative ○ 207 (2+)
○ 533 Trace ○ 206 (3+)
○ 208 (1+) ○ 205 (4+)

CM-02

100 ○ 110 Negative ○ 207 (2+)
○ 533 Trace ○ 206 (3+)
○ 208 (1+) ○ 205 (4+)

Reporting Method 3 (Unit of Measure = mg/dL)

Method Code 110 ☐☐☐☐ Instrument Code 120 ☐☐☐☐ Exception Code 130 ○ 11 ○ 33

CM-01

140 ○ 110 Negative ○ 376 6.0 - 10.0
○ 288 0.5 - 1.0 ○ 377 >10.0
○ 290 2.0 - 4.0

CM-02

150 ○ 110 Negative ○ 376 6.0 - 10.0
○ 288 0.5 - 1.0 ○ 377 >10.0
○ 290 2.0 - 4.0

***Bilirubin and Urobilinogen Testing** (visual read methods): Proficiency testing specimens may give a slightly atypical color development when examined visually. If this occurs, the specimen should be reported based on the intensity of the color.

HCC2-A
2017

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

Blood or Hemoglobin

Alert! Select only one reporting method. Do not select more than one reporting area.

Reporting Method 1

010 Method Code ____ 020 Instrument Code ____ 030 ○ 11 Exception Code ○ 33

CM-01

040 ○ 120 Negative
○ 369 Trace/Small
○ 368 Positive/Moderate
○ 361 Marked Positive/Large

CM-02

050 ○ 120 Negative
○ 369 Trace/Small
○ 368 Positive/Moderate
○ 361 Marked Positive/Large

Reporting Method 2

060 Method Code ____ 070 Instrument Code ____ 080 ○ 11 Exception Code ○ 33

CM-01

090 ○ 110 Negative
○ 533 Trace
○ 208 (1+)
○ 207 (2+)
○ 206 (3+)
○ 205 (4+)
○ 203 (5+)

CM-02

100 ○ 110 Negative
○ 533 Trace
○ 208 (1+)
○ 207 (2+)
○ 206 (3+)
○ 205 (4+)
○ 203 (5+)

Reporting Method 3 (Unit of Measure = Ery/µL)

110 Method Code ____ 120 Instrument Code ____ 130 ○ 11 Exception Code ○ 33

CM-01

140 ○ 110 Negative
○ 192 5 - 25
○ 193 50 - 150
○ 194 250

CM-02

150 ○ 110 Negative
○ 192 5 - 25
○ 193 50 - 150
○ 194 250

Reporting Method 4 (Unit of Measure = mg/dL)

160 Method Code ____ 170 Instrument Code ____ 180 ○ 11 Exception Code ○ 33

CM-01

190 ○ 110 Negative
○ 362 ±0.03
○ 363 0.06 - 0.10
○ 287 0.20 - 0.50
○ 364 ≥ 1.0

CM-02

200 ○ 110 Negative
○ 362 ±0.03
○ 363 0.06 - 0.10
○ 287 0.20 - 0.50
○ 364 ≥ 1.0

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

HCC2-A
2017

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

Leukocyte Esterase

Alert! Select only one reporting method. Do not select more than one reporting area.

Reporting Method 1

010 Method Code [ ] 020 Instrument Code [ ] 030 Exception Code ○ 11 ○ 33

CM-01

040 ○ 120 Negative ○ 366 Moderate ○ 533 Trace ○ 367 Large ○ 365 Small

CM-02

050 ○ 120 Negative ○ 366 Moderate ○ 533 Trace ○ 367 Large ○ 365 Small

Reporting Method 2

060 Method Code [ ] 070 Instrument Code [ ] 080 Exception Code ○ 11 ○ 33

CM-01

090 ○ 110 Negative ○ 207 (2+) ○ 533 Trace ○ 206 (3+) ○ 208 (1+) ○ 205 (4+)

CM-02

100 ○ 110 Negative ○ 207 (2+) ○ 533 Trace ○ 206 (3+) ○ 208 (1+) ○ 205 (4+)

Reporting Method 3 (Unit of Measure = µL)

110 Method Code [ ] 120 Instrument Code [ ] 130 Exception Code ○ 11 ○ 33

CM-01

140 ○ 110 Negative ○ 414 25 ○ 415 75 or 100 ○ 416 250 or 500

CM-02

150 ○ 110 Negative ○ 414 25 ○ 415 75 or 100 ○ 416 250 or 500

CAP

HCC2-A
2017

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

Nitrite

010 Method Code ____ 020 Instrument Code ____ 030 ○ 11 Exception Code ○ 33

CM-01	CM-02
040 ○ 209 Negative ○ 210 Positive	050 ○ 209 Negative ○ 210 Positive

Urobilinogen*

Alert! Select only one reporting method. Do not select more than one reporting area.

Reporting Method 1

060 Method Code ____ 070 Instrument Code ____ 080 ○ 11 Exception Code ○ 33

CM-01	CM-02
090 ○ 110 Negative ○ 208 (1+) ○ 207 (2+) ○ 206 (3+) ○ 205 (4+)	100 ○ 110 Negative ○ 208 (1+) ○ 207 (2+) ○ 206 (3+) ○ 205 (4+)

Reporting Method 2 (Unit of Measure = mg/dL)

110 Method Code ____ 120 Instrument Code ____ 130 ○ 11 Exception Code ○ 33

CM-01	CM-02
140 ○ 417 Negative or 0.0 - 0.2 mg/dL or < 3.2 µmol/L ○ 418 1.0 or < 2.0 mg/dL or 16 µmol/L or < 35 µmol/L** ○ 419 2.0/3.0 mg/dL or 34 µmol/L or ≥ 35 µmol/L or < 70 µmol/L ○ 420 4.0 or 4.0/6.0 mg/dL or ≥ 70 µmol/L or < 140 µmol/L ○ 421 ≥ 8.0 or 12.0 mg/dL or ≥ 140 µmol/L or 200 µmol/L	150 ○ 417 Negative or 0.0 - 0.2 mg/dL or < 3.2 µmol/L ○ 418 1.0 or < 2.0 mg/dL or 16 µmol/L or < 35 µmol/L** ○ 419 2.0/3.0 mg/dL or 34 µmol/L or ≥ 35 µmol/L or < 70 µmol/L ○ 420 4.0 or 4.0/6.0 mg/dL or ≥ 70 µmol/L or < 140 µmol/L ○ 421 ≥ 8.0 or 12.0 mg/dL or ≥ 140 µmol/L or 200 µmol/L

***Bilirubin and Urobilinogen Testing** (visual read methods): Proficiency testing specimens may give a slightly atypical color development when examined visually. If this occurs, the specimen should be reported based on the intensity of the color.

****Note:** < 35 µmol/L for ARKRAY Aution MAX users only.

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2017

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

Urine, hCG

Method Code 010 20 52

020 ○ 11 Exception Code ○ 33

CM-01	CM-02
030 ○ 120 Negative	040 ○ 120 Negative
○ 210 Positive	○ 210 Positive

CAP

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.

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Signatures will not display when viewed online.