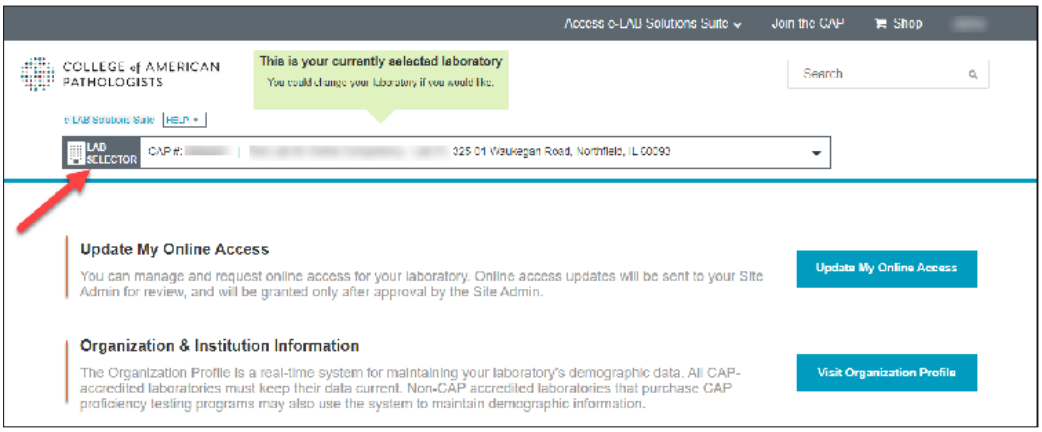
How to Manage CMS Analyte Reporting Selections

Proficiency testing (PT) is required for regulated analytes, as defined in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. The CAP provides a number of programs that meet these requirements. Depending on the programs you have ordered, you may have one or more options (or kits) from which to report a given regulated analyte. The Centers for Medicare and Medicaid Services (CMS) only accepts one performance score per regulated analyte. To determine which scores are submitted to CMS, the CAP follows a predefined kit hierarchy/ precedence, unless provided with alternate instructions/preferences from the laboratory. The CMS Analyte Reporting Selections tool provides a real-time summary of this information, as well as the ability to make changes to the kit reporting hierarchy or to indicate that testing has been discontinued for an analyte.

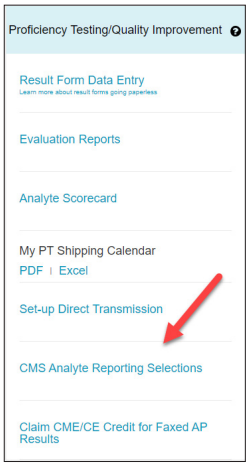
If your laboratory is not subject to the regulations of CLIA, then performance scores will not be reported to CMS. However, it is still important that you identify your preferences, as this information is used to determine your scoring summary on evaluations that contain regulated analytes.

How do I access my laboratory's CMS Reporting Selections?

1. Select a laboratory via the **Lab Selector.**
   Note: Users who have access to only one laboratory may skip this step. That laboratory will show as the default.



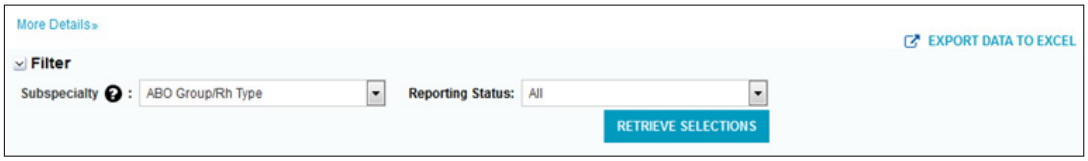
2. Click **CMS Analyte Reporting Selections.**



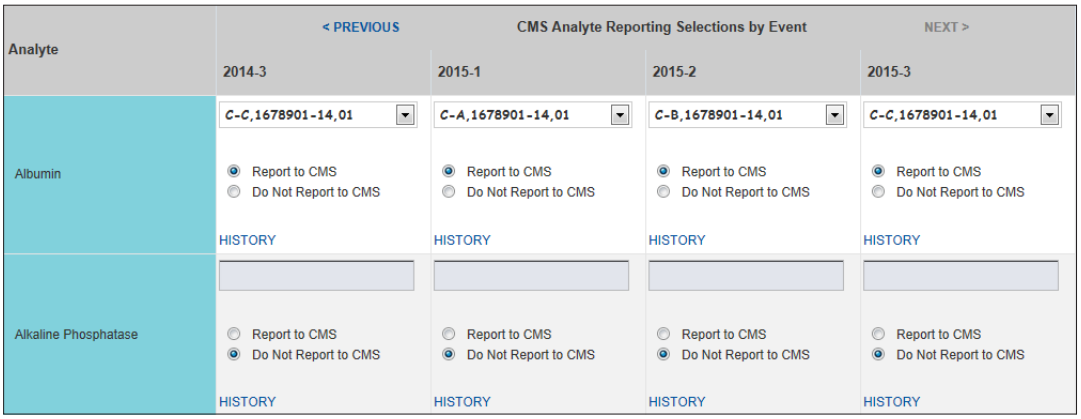
Note: This document is populated with all of the regulated analytes for which you have ordered PT. If you have not ordered a program that contains a given regulated analyte, then that analyte will not appear on this report. No further action is required.

In order to make updates within this tool, you must have the "Manage Regulatory Reporting" permission granted by your site administrator.

3. Select a Subspecialty and Reporting Status using the Filter options and click **Retrieve Selections.** You can either choose to see all the analytes within a subspecialty or just those that you have selected to report (or not report) to CMS. Please note that only those analytes for which you have enrollment in at least one event will be displayed.



The CMS Analyte Reporting Selections tool will display the reporting selections (or preferences) for each analyte by event. The four most current/future events with enrollment will be displayed by default. You may navigate to and from prior events by using the previous/next menu options on the top and bottom of the table. As many as nine events (or three years) will be accessible.

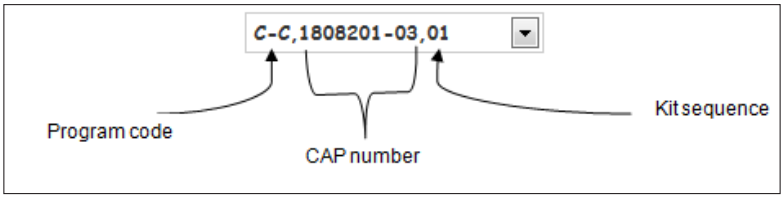


An analyte event can be in one of five different statuses.

- **Report to CMS** – This means that performance scores for the analyte will be reported to CMS (for labs subject to CLIA regulations with a reporting relationship to CMS). If results for the analyte are not submitted for at least one of the enrolled kits, then a score of zero will be reported. Selecting “Report to CMS” for an analyte event will automatically be applied to all future events for that analyte.
- **Do Not Report to CMS** – Although the analyte is included in a kit for the event, no performance scores will be reported, regardless of whether results are submitted for the analyte. This status is appropriate if your lab has discontinued testing the given analyte or does not want scores to be reported from CAP for the analyte. It is very important that your laboratory indicate in advance that testing is no longer performed for an analyte to avoid receiving a score of zero. Selecting “Do Not Report to CMS” for an analyte event will automatically be applied to all future events for that analyte.
- **Locked For Evaluation** – The analyte event is displayed as inactive (or dimmed) and no changes are allowed. This status occurs when one of the kits for the analyte event has been evaluated. Updates to reporting selections can only be made prior to evaluation.
- **No Enrollment for Analyte Event** – Your laboratory is not enrolled in any kits for the given analyte event.
- **Unspecified** – The reporting status for the analyte has not been selected, but your laboratory has ordered kits that contain the analyte. If you return results for this analyte, then your reporting status will automatically be turned on and

the performance score will be reported to CMS per the kit hierarchy. If you do not want to report performance scores for this analyte, then you must select “Do Not Report to CMS.” If you do not test for this analyte, then no action is necessary. No penalty will be accessed for not returning results when the analyte event is in this status. This status cannot be selected by the laboratory, but is rather the default status for an analyte when it is ordered for the first time. Additionally, for CAP accreditation participants maintaining their laboratory test menu, if you remove all test/activities associated with an analyte, then future events for the analyte will automatically return to this status.

For analytes that have a “Report to CMS” selection, a dropdown list of kits is displayed. This list includes all the kits (one or more) your lab has ordered for a given reporting event that contain the respective analyte.



Kits are listed in hierarchical order on each dropdown by mailing code, CAP number (lowest to highest) and kit sequence (lowest to highest). Performance scores from the first kit (default display) will be reported to CMS. If no results are received for the first kit, scores will be reported from the next kit on the list…and so forth. To move a kit to the top of the reporting hierarchy, select it from the dropdown list. A selection made for one event will automatically be applied to future events for that analyte, as applicable.

What is the Kit Sequence number?

The kit sequence is an ordinal number assigned to differentiate multiple kits in the same program mailing. For example, if your laboratory orders three kits from the same program, the first kit will be assigned kit sequence 01, the second kit will be assigned kit sequence 02 and the third kit will be assigned kit sequence 03. These kit sequence numbers will be the same from mailing to mailing and will allow you to keep track of which kit is used for reporting on a particular instrument or within a certain area of the laboratory. The kit sequence should not be confused with the eight-digit ‘kit number’ that is used to uniquely identify each kit provided by the CAP.

What is the Kit Reporting Hierarchy?

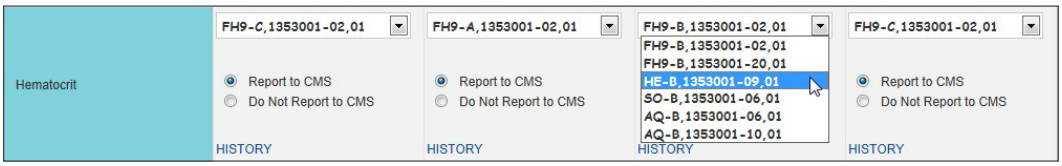
To ensure compliance with CMS regulations and to facilitate the process of reporting a single performance score per analyte event that is consistent and logical, the CAP follows a kit reporting hierarchy. The kit reporting hierarchy refers to the hierarchical order or precedence CAP assigns kits for reporting to CMS. Because your laboratory may submit results from one or more kits and not necessarily all kits, the kit reporting hierarchy will make sure that your laboratory’s performance score for each analyte is selected from a kit that has results and that this selection process is repeated for each event. If your laboratory does not submit results for an analyte from the first or highest kit in the hierarchy, CAP will look for results from the next kit and so forth until all available kits have been evaluated.

The order of the kit reporting hierarchy is sequenced first by mailing code, then by CAP number (lowest to highest) and finally by kit sequence (lowest to highest). The Mailing Code Precedence by Analyte is available at the end of this document and identifies the default order by which mailing codes are placed in the kit reporting hierarchy. The CMS Analyte Reporting Selections tool allows you to change the default kit reporting hierarchy for an analyte by moving one kit to the top of the list. When this is done, the remaining kits in the list will return to the default hierarchy and performance

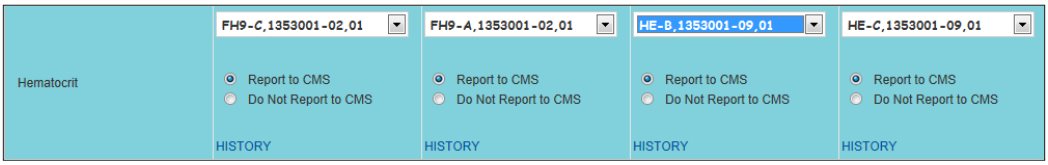
scores will be reported from the highest kit with submitted results. In other words, you cannot rearrange the entire kit reporting hierarchy, only the first kit. Changes to the hierarchy will automatically be applied to future events for the analyte, as applicable.

How do I view the Kit Reporting Hierarchy?

For analyte events that are not locked for evaluation and set to “Report to CMS,” the kit reporting hierarchy can be viewed by clicking the dropdown.



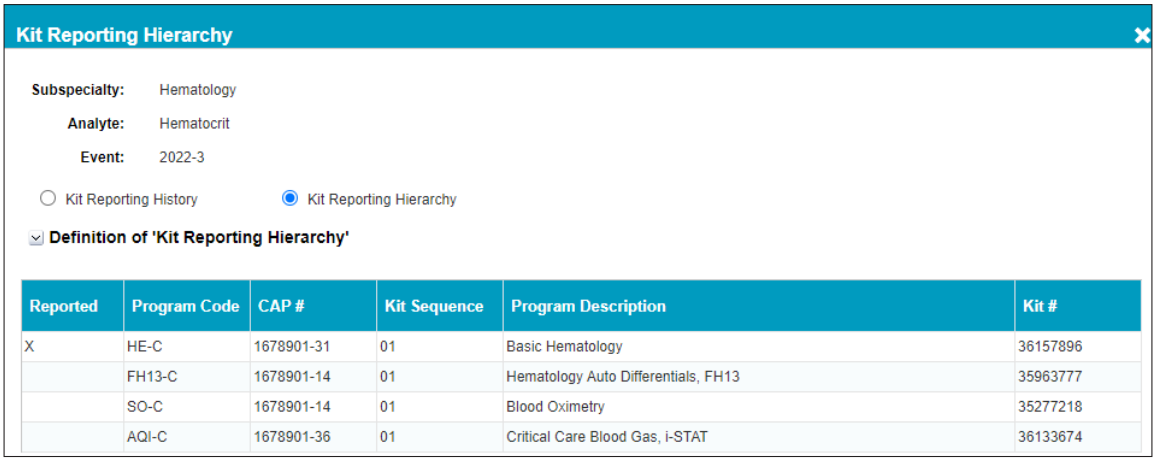
In the above example, selecting “HE-C, 1678901-31, 01” from the list will move that kit to the top of the hierarchy. In turn, future events for the same analyte will be adjusted accordingly (as shown below), so that you do not need to repeat this process for each event. If you would like a future event to have different settings, then those adjustments can be made on an event by event basis. Just know that any events subsequent to the one being adjusted will automatically be updated to match.



If at some point you discontinue your enrollment in a mailing that you have moved to the top of the hierarchy, the default hierarchy for the remaining or new mailings will be maintained.

As soon as one of the kits in the hierarchy is evaluated, the event is locked and no further changes to the hierarchy or reporting status can be made to that event. The analyte event will appear dim and be inactive. This is done to prevent selective reporting of more favorable results. Only future events (prior to evaluation) can be updated.

To view the kit reporting hierarchy for past (or locked) events, you can click the HISTORY link for that event and select the Kit Reporting Hierarchy radio button.



Reported	Program Code	CAP #	Kit Sequence	Program Description	Kit #
X	HE-C	1678901-31	01	Basic Hematology	36157896
	FH13-C	1678901-14	01	Hematology Auto Differentials, FH13	35963777
	SO-C	1678901-14	01	Blood Oximetry	35277218
	AQI-C	1678901-36	01	Critical Care Blood Gas, i-STAT	36133674

This screen will show the hierarchical list of kits for the event that were eligible for reporting the analyte, including the specific kit numbers and a description of the program. Additionally, the “Reported” column will identify the kit from which the performance score was ultimately selected in the hierarchy. It should be noted that the only way a score can be reported from a kit other than the one at the top of the list is if results for the analyte were not submitted. In the example above, if Hematocrit wasn’t submitted in HE-C, then the score would have been taken from the next in the hierarchy – in this case, FH13-C.

It should also be noted that it does not matter when a given kit is evaluated, the kit reporting hierarchy will wait for the kits higher on the list to be evaluated before reporting a score from a kit lower on the list.

What is the Kit Reporting History?

The kit reporting history can be accessed by clicking on the HISTORY link for an analyte event.

Each analyte event will have its own unique history detailing the activity that was completed, including what was changed, by whom it was changed and when it was changed. Changes may include updates to the kit reporting hierarchy, as well as when reporting to CMS was turned on or off for the analyte.

There are five different “Activity” types that can appear:

- **Changed Reporting Preference To** – This indicates that a kit has been moved to the top of the kit reporting hierarchy. The kit that was elevated will be listed in the “Kit Name” column. The event in which this change was made will be listed in the “Note” column. Remember that a change made to a prior event will automatically be made to future events.
- **Turned Reporting On** – As the name suggests, this indicates that reporting for the analyte was turned on and performance scores will be reported to CMS. The “Kit Name” column will be blank for this type of activity and the “Note” column will specify the event this change was initiated.
- **Turned Reporting Off** – Conversely, this indicates that reporting for the analyte was turned off, either because testing has been discontinued for the analyte or the lab no longer wants to report performance scores from CAP. The “Kit Name” column will be blank for this type of activity and the “Note” column will specify the event this change was initiated.
- **Locked For Evaluation** – This indicates that one of the kits for the analyte event has been evaluated and no further changes to the hierarchy or reporting status can be made to that event.
- **Reset by CAP** – For CAP accreditation participants maintaining their laboratory test menu, if all test/activities associated with an analyte are removed, then future events for the analyte will be automatically reset to the “unspecified” status as defined above.

How does the 'Export Data to Excel' function work?

Clicking on EXPORT DATA TO EXCEL will download your laboratory's analyte reporting selections to an Excel spreadsheet, for all subspecialties and events, regardless of filter settings. The format of the spreadsheet will include columns for subspecialty, analyte and the nine most recent events. For each event, Y (Reported to CMS) or N (Do Not Report to CMS) will be displayed for the analyte. A dash (-) indicates a status of No Enrollment for Analyte Event or Unspecified (see above for definitions). The kit reporting hierarchy detail for each analyte will not be displayed in this report. Please note again that data prior to the first event of 2015 (2015-1) is not available in this tool and, therefore, not applicable in the Excel export.

	A	B	C	D	E
1	**Subspecialty**	**Analyte**	**2015-3**	**2015-2**	**2015-1**
2	ABO Group/Rh Type	ABO Group	Y	Y	Y
3	ABO Group/Rh Type	Rh (D) Type	Y	Y	Y
4	Antibody Identification	Antibody Identification	Y	Y	Y
5	Bacteriology	Antimicrobial Susceptibility	Y	Y	Y
6	Bacteriology	Bacterial Antigen Detection	Y	Y	Y
7	Bacteriology	Bacterial Identification	Y	Y	Y
8	Bacteriology	Gram Stain	Y	Y	Y
9	Compatibility Testing	Compatibility Testing	Y	Y	Y
10	Endocrinology	Cortisol	N	N	N
11	Endocrinology	hCG	Y	Y	Y
12	Endocrinology	T3 Uptake/Related Tests	-	-	-
13	Endocrinology	Thyroxine (T4, Total)	Y	Y	Y
14	Endocrinology	Thyroxine, Free (T4, Free)	Y	Y	Y
15	Endocrinology	Triiodothyronine (T3)	N	N	N
16	Endocrinology	TSH	Y	Y	Y
17	General Immunology	Alpha-1-Antitrypsin	-	-	-
18	General Immunology	Alpha-Fetoprotein	Y	Y	Y
19	General Immunology	Anti-HIV	Y	Y	Y

Mailing Code Precedence by Analyte

ANALYTE	MAILING CODE PRECEDENCE — FIRST TO LAST	SUBSPECIALTY
ABO group	J, J1, JAT	ABO Group/Rh Type
Acetaminophen	C	Routine Chemistry
Acid-fast stain	E, E1	Mycobacteriology
Albumin	C	Routine Chemistry
Alkaline phosphatase	C	Routine Chemistry
Alpha-1-antitrypsin	S	General Immunology
Alpha-fetoprotein	K, FP	General Immunology
ALT	C	Routine Chemistry
Amylase	C	Routine Chemistry
Antibody detection, unexpected	J, JAT	Unexpected Antibody Det
Antibody identification	J, JAT	Antibody Identification
Anti-HBc	VM	General Immunology
Anti-HBs	VM	General Immunology
Anti-HCV	VM	General Immunology
Anti-HIV	AHIV, VM	General Immunology
Antimicrobial susceptibility	D, RMC, D2	Bacteriology
Antimycobacterial susceptibility*	E *no longer regulated starting in 2025	Mycobacteriology
Antinuclear antibody, qual	S	General Immunology
Antistreptolysin O, qual	S	General Immunology
AST	C	Routine Chemistry
Bacterial antigen detection	D, D6, RMC, CDF, MC4, HC3	Bacteriology
Bacterial identification	D, RMC, D1, D2, D3, D8, MC4, MRS5, MRS5M, HC6, HC7, IDR, VS, GIP5, BCM, IDM5, IDPN, STIM, BDP5, BDPV5	Bacteriology
Bacterial toxin detection	GIP5, CDF, D, ST, SP	Bacteriology
Bilirubin, total	C, NB	Routine Chemistry
Blood gas, PCO2	AQ, AQH, AQIS	Routine Chemistry
Blood gas, pH	AQ, AQH, AQIS	Routine Chemistry
Blood gas, PO2	AQ, AQH, AQIS	Routine Chemistry
Blood lead	BL	Toxicology

ANALYTE	MAILING CODE PRECEDENCE — FIRST TO LAST	SUBSPECIALTY
B-type natriuretic peptide (BNP)	BNP5, PCARM	Routine Chemistry
Calcium, total	C	Routine Chemistry
Cancer antigen (CA) 125	K	Endocrinology
Carcinoembryonic antigen (CEA)	K	Endocrinology
Carbamazepine	C	Toxicology
Cell identification	BCP, BCPV	Hematology
Chloride	C, AQ, AQH, AQIS	Routine Chemistry
Cholesterol, HDL	C	Routine Chemistry
Cholesterol, LDL	C	Routine Chemistry
Cholesterol, total	C	Routine Chemistry
CK isoenzymes (CK-MB)	CAR, PCARM	Routine Chemistry
Carbon dioxide (CO_2) includes tCO_2	C, AQ, AQH, AQIS	Routine Chemistry
Compatibility testing	J, JAT	Compatibility Testing
Complement C3	S	General Immunology
Complement C4	S	General Immunology
Cortisol	K, C	Endocrinology
Creatine kinase	C	Routine Chemistry
Creatinine	C, AQ, AQH, AQIS, WBCR	Routine Chemistry
C-reactive protein (high sensitivity)	HSCRP	Routine Chemistry
Digoxin	C	Toxicology
Erythrocyte count (RBC)	HE, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17	Hematology
Estradiol	Y	Endocrinology
Ethanol	AL2, AL1	Toxicology
Ethosuximide*	C *no longer regulated starting in 2025	Toxicology
Ferritin	C, K	Routine Chemistry
Fibrinogen	CGL	Hematology
Folate, serum	K	Endocrinology
Follicle stimulating hormone (FSH)	Y	Endocrinology

ANALYTE	MAILING CODE PRECEDENCE — FIRST TO LAST	SUBSPECIALTY
Fungal antigen	F, F1, CRYP	Mycology
Gamma glutamyl transferase (GGT)	C	Routine Chemistry
Gentamicin	C	Toxicology
Glucose	C, AQ, AQH, AQIS	Routine Chemistry
Gram stain (includes Gram stain morphology)	D5, D, RMC, D2, D3	Bacteriology
hCG	S, K, C, FP	Endocrinology
Hematocrit	HE, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17, SO, AQ, AQH, AQIS	Hematology
Hemoglobin	HE, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17, SO, AQ, AQH, AQIS	Hematology
Hemoglobin A1c	GH5, GH5I	Routine Chemistry
HBeAg	VM	General Immunology
HBsAg	VM	General Immunology
IgA	S	General Immunology
IgE	S, K, SE	General Immunology
IgG	S	General Immunology
IgM	S	General Immunology
Infectious mononucleosis	S	General Immunology
Iron, Total	C	Routine Chemistry
LD	C	Routine Chemistry
LD isoenzymes*	CAR *no longer regulated starting in 2025	Routine Chemistry
Leukocyte count (WBC)	HE, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17	Hematology
Lithium	C	Toxicology
Luteinizing hormone (LH)	Y	Endocrinology
Magnesium	C	Routine Chemistry
Mycobacterial identification	E, E1, MTR5	Mycobacteriology
Mycological identification	F, F1, F3, YBC, MVP, VS, IDM5	Mycology
Parasite antigen	P, RML5	Parasitology
Parasite identification	P, BP, GIP5, TVG5, VS, STIM, MVP	Parasitology
Parathyroid hormone (PTH)	PTH	Endocrinology

ANALYTE	MAILING CODE PRECEDENCE — FIRST TO LAST	SUBSPECIALTY
Phenobarbital	C	Toxicology
Phenytoin	C	Toxicology
Phosphorus	C	Routine Chemistry
Platelet count	HE, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17	Hematology
Potassium	C, AQ, AQI	Routine Chemistry
Primidone*	C *no longer regulated starting in 2025	Toxicology
Pro B-natriuretic peptide (pro-BNP)	BNP5, PCARM	Routine Chemistry
Procainamide/Metabolites (NAPA)*	C *no longer regulated starting in 2025	Toxicology
Progesterone	Y	Endocrinology
Prolactin	Y	Endocrinology
Prostate specific antigen (PSA), total	K	Endocrinology
Protein, total	C	Routine Chemistry
Prothrombin time	CGL, WP3, WP4, WP6, WP9	Hematology
PTT	CGL	Hematology
Quinidine*	C *no longer regulated starting in 2025	Toxicology
Rh (D) type	J, J1, JAT	ABO Group/Rh Type
Rheumatoid Factor, qual	S	General Immunology
Rubella, qual	S	General Immunology
Salicylate	C	Routine Chemistry
Sodium	C, AQ, AQH, AQIS	Routine Chemistry
Syphilis serology	G	Syphilis Serology
T3 uptake/related tests	K, C	Endocrinology
Testosterone	Y	Endocrinology
Theophylline	C	Toxicology
Thyroxine (T4, total)	K, C	Endocrinology
Thyroxine, free (T4, free)	K, C	Endocrinology
Tobramycin	C	Toxicology
Total, iron binding capacity (TIBC)	C	Routine Chemistry

ANALYTE	MAILING CODE PRECEDENCE — FIRST TO LAST	SUBSPECIALTY
Triglycerides	C	Routine Chemistry
Triiodothyronine (T3)	K, C	Endocrinology
Troponin I	CAR, PCARM	Routine Chemistry
Troponin T*	NONE *High-sensitivity Troponin T available	Routine Chemistry
TSH	K, C	Endocrinology
Urea nitrogen	C, AQ, AQH, AQIS	Routine Chemistry
Uric acid	C	Routine Chemistry
Valproic acid	C	Toxicology
Vancomycin	C	Routine Chemistry
Viral antigen detection	VR4, CVAG, VR2	Virology
Viral identification	VR1, HC4, IDR, ID3, ID5, GIP5, IDM5, IDPN, CHPV, COVM	Virology
Vitamin B_{12}	K	Endocrinology
WBC differential	FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17	Hematology