

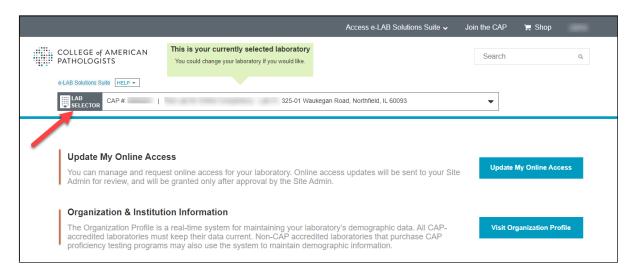
# **How to Manage CMS Analyte Reporting Selections**

Proficiency testing (PT) is required for regulated analytes, as defined in Subpart I, Proficiency Testing Programs for Nonwaived Testing, of the CLIA regulations. PT is required for the test system/assay that your laboratory uses as the primary method for patient testing. 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 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 program hierarchy/precedence. Your laboratory has the option to report from the program that best aligns with your laboratory's primary method. This tool can be used to modify the precedence or to indicate that testing has been discontinued for an analyte. Please note that no changes will be allowed after the evaluation is complete. The CMS Analyte Reporting Selections tool provides a real-time summary of this information, as well as the ability to make changes to the program reporting hierarchy or to indicate that testing has been discontinued for an analyte. Your laboratory should regularly review the kit reporting hierarchy and adjust as necessary to ensure the selected program includes the laboratory's primary instrument. If your laboratory has multiple instruments designated as primary, PT can be rotated among the primary instruments, from mailing to mailing, as appropriate.

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?

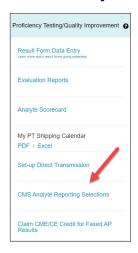
Select a laboratory via the Lab Selector.
 Note: Users who have access to only one laboratory may skip this step. That laboratory will show as the default.





#### Laboratory Quality Solutions

2. Click CMS Analyte Reporting Selections.



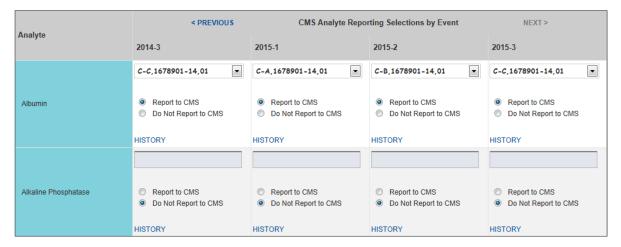
*Note:* This document is populated with all of the regulated analytes for which you have ordered PT. If you have not ordered a program that contains a given regulated analyte, then that analyte will not appear on this report. No further action is required.

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

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.



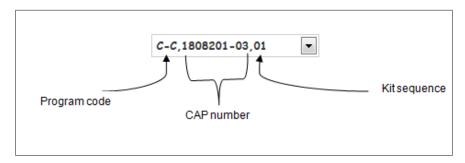
The CMS Analyte Reporting Selections tool will display the reporting selections (or preferences) for each analyte by event. The four most current/future events with enrollment will be displayed by default. You may navigate to and from prior events by using the previous/next menu options on the top and 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 laboratories 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 programs, 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 program for the event, no performance scores will be reported, regardless of whether results are submitted for the analyte. This status is appropriate if your laboratory 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 programs 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 programs for the given analyte event.
- Unspecified The reporting status for the analyte has not been selected, but your laboratory has ordered programs 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 program 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 programs is displayed. This list includes all the programs (one or more) your laboratory has ordered for a given reporting event that contain the respective analyte.



Programs are listed in hierarchical order on each dropdown by mailing code, CAP number (lowest to highest) and program sequence (lowest to highest). Performance scores from the first program (default display) will be reported to CMS. If no results are received for the first program, scores will be reported from the next program on the list, and so forth. To move a program 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. Please adjust the default hierarchy as necessary to ensure the program with your primary method is selected for reporting.



#### 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 program reporting hierarchy. The program reporting hierarchy refers to the hierarchical order or precedence CAP assigns programs for reporting to CMS. Because your laboratory may submit results from one or more programs and not necessarily all programs, the program reporting hierarchy will make sure that your laboratory's performance score for each analyte is selected from a program 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 program in the hierarchy, CAP will look for results from the next program and so forth until all available programs have been evaluated. Please adjust the default hierarchy as necessary to ensure the program with your primary method is selected for reporting.

The order of the program reporting hierarchy is sequenced first by mailing code, then by CAP number (lowest to highest) and finally by program 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 program reporting hierarchy. The CMS Analyte Reporting Selections tool allows you to change the default program reporting hierarchy for an analyte by moving one program to the top of the list. When this is done, the remaining programs in the list will return to the default hierarchy and performance scores will be reported from the highest program with submitted results. In other words, you cannot rearrange the entire program reporting hierarchy, only the first program. Changes to the hierarchy will automatically be applied to future events for the analyte, as applicable.

#### **How do I view the Program Reporting Hierarchy?**

For analyte events that are not locked for evaluation and set to "Report to CMS," the program 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 program 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. *Note:* Any events subsequent to the one being adjusted will automatically be updated to match.



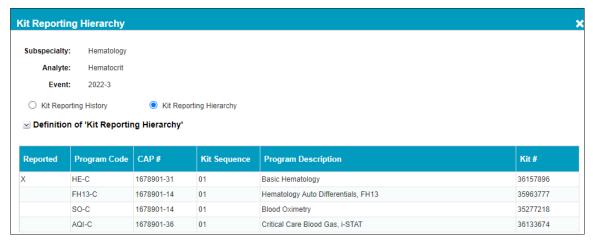


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If at some point you discontinue your enrollment in a mailing that you have moved to the top of the hierarchy, the default hierarchy for the remaining or new mailings will be maintained.

As soon as one of the programs 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.



This screen will show the hierarchical list of programs 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 program 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 laboratory no longer wants to report performance scores from the 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.

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



# **Mailing Code Precedence by Analyte**

| ANALYTE                           | MAILING CODE PRECEDENCE —<br>FIRST TO LAST  | SUBSPECIALTY            |
|-----------------------------------|---|-------------------------|
| ABO group                         | JAT, J, J1  | ABO Group/Rh Type       |
| Acetaminophen                     | С   | Routine Chemistry       |
| Acid-fast stain                   | E, E1   | Mycobacteriology        |
| Albumin                           | С   | Routine Chemistry       |
| Alkaline phosphatase              | С   | Routine Chemistry       |
| Alpha-1-antitrypsin               | S   | General Immunology      |
| Alpha-fetoprotein                 | K, FP   | General Immunology      |
| ALT                               | С   | Routine Chemistry       |
| Amylase                           | С   | Routine Chemistry       |
| Antibody detection, unexpected    | JAT, J  | Unexpected Antibody Det |
| Antibody identification           | JAT, J  | 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                               | С   | Routine Chemistry       |
| Bacterial antigen detection       | D, D6, RMC, CDF, MC4  | 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         | D, GIP5, CDF, 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              |

| Laboratory | Qualit | y So | lutions |
|------------|--------|------|---------|
|------------|--------|------|---------|

| ANALYTE   | MAILING CODE PRECEDENCE —<br>FIRST TO LAST          | SUBSPECIALTY          |
|---|---|-----------------------|
| B-type natriuretic peptide (BNP)                            | BNP5, PCARM   | Routine Chemistry     |
| Calcium, total  | С   | Routine Chemistry     |
| Cancer antigen (CA) 125                                     | К   | Endocrinology         |
| Carcinoembryonic antigen (CEA)                              | К   | Endocrinology         |
| Carbamazepine   | С   | Toxicology            |
| Cell identification   | BCP, BCPV   | Hematology            |
| Chloride  | C, AQ, AQH, AQIS                                    | Routine Chemistry     |
| Cholesterol, HDL  | С   | Routine Chemistry     |
| Cholesterol, LDL  | С   | Routine Chemistry     |
| Cholesterol, total  | С   | Routine Chemistry     |
| CK isoenzymes (CK-MB)                                       | CAR, PCARM  | Routine Chemistry     |
| Carbon dioxide (CO <sub>2</sub> ) includes tCO <sub>2</sub> | C, AQ, AQH, AQIS                                    | Routine Chemistry     |
| Compatibility testing                                       | JAT, J  | Compatibility Testing |
| Complement C3   | S   | General Immunology    |
| Complement C4   | S   | General Immunology    |
| Cortisol  | K, C  | Endocrinology         |
| Creatine kinase   | С   | Routine Chemistry     |
| Creatinine  | C, AQ, AQH, AQIS, WBCR                              | Routine Chemistry     |
| C-reactive protein (high sensitivity)                       | HSCRP   | Routine Chemistry     |
| Digoxin   | С   | Toxicology            |
| Erythrocyte count (RBC)                                     | HE, FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17 | Hematology            |
| Estradiol   | Υ   | Endocrinology         |
| Ethanol   | AL2, AL1  | Toxicology            |
| Ethosuximide*   | C *no longer regulated starting in 2025             | Toxicology            |
| Ferritin  | C, K  | Routine Chemistry     |
| Fibrinogen  | CGL   | Hematology            |
| Folate, serum   | К   | Endocrinology         |
| Follicle stimulating hormone (FSH)                          | Υ   | Endocrinology         |



| ANALYTE                                     | MAILING CODE PRECEDENCE —<br>FIRST TO LAST                             | SUBSPECIALTY       |
|---|--|--------------------|
| Fungal antigen                              | F, F1, CRYP  | Mycology           |
| Gamma glutamyl transferase (GGT)            | С  | Routine Chemistry  |
| Gentamicin                                  | С  | 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                                 | С  | Routine Chemistry  |
| LD  | С  | 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                                     | С  | Toxicology         |
| Luteinizing hormone (LH)                    | Υ  | Endocrinology      |
| Magnesium                                   | С  | 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 —<br>FIRST TO LAST          | SUBSPECIALTY       |
|--|---|--------------------|
| Phenobarbital                          | С   | Toxicology         |
| Phenytoin                              | С   | Toxicology         |
| Phosphorus                             | С   | 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                           | Υ   | Endocrinology      |
| Prolactin                              | Υ   | Endocrinology      |
| Prostate specific antigen (PSA), total | К   | Endocrinology      |
| Protein, total                         | С   | 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                            | JAT, J, J1  | ABO Group/Rh Type  |
| Rheumatoid Factor, qual                | S   | General Immunology |
| Rubella, qual                          | S   | General Immunology |
| Salicylate                             | С   | Routine Chemistry  |
| Sodium                                 | C, AQ, AQH, AQIS                                    | Routine Chemistry  |
| Syphilis serology                      | G   | Syphilis Serology  |
| T3 uptake/related tests                | K, C  | Endocrinology      |
| Testosterone                           | Υ   | Endocrinology      |
| Theophylline                           | С   | Toxicology         |
| Thyroxine (T4, total)                  | K, C  | Endocrinology      |
| Thyroxine, free (T4, free)             | K, C  | Endocrinology      |
| Tobramycin                             | С   | Toxicology         |
| Total, iron binding capacity (TIBC)    | С   | Routine Chemistry  |



| ANALYTE                 | MAILING CODE PRECEDENCE —<br>FIRST TO LAST            | SUBSPECIALTY      |
|-------------------------|---|-------------------|
| Triglycerides           | С   | 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               | С   | Routine Chemistry |
| Valproic acid           | С   | Toxicology        |
| Vancomycin              | С   | Routine Chemistry |
| Viral antigen detection | VR4, CVAG, VR2  | Virology          |
| Viral identification    | HC4, IDR, VR1, ID3, ID5, GIP5, IDM5, IDPN, CHPV, COVM | Virology          |
| Vitamin B <sub>12</sub> | К   | Endocrinology     |
| WBC differential        | FH1, FH2, FH3, FH4, FH9, FH10, FH13, FH16, FH17       | Hematology        |