

## New Chemistry Platforms at Vanderbilt Medical Laboratories

Vanderbilt Medical Laboratories have upgraded chemistry testing platforms. This change enables:

- Reduced sample volume requirements to run tests.
- Improved turnaround time through automation.
- Improved consistency and quality of results by measuring common interfering conditions, namely hemolysis, lipemia, and icterus.
- Improved lab staff efficiency.
- Improved ability to bring testing in-house to VML.

Vanderbilt Medical Laboratories at MetroCenter will implement the new chemistry platforms on March 1, 2024, whereas all other lab locations will upgrade their testing platforms over the next few years. Further communications about that timeline and process will be forthcoming.

# The process for ordering lab tests will be the same. Changes that will impact your practice include:

- Different reference ranges will exist in the enterprise for the same test, depending on where the test is performed.
  - Two different chemistry platforms will run the same tests until the enterprise standardizes equipment.
  - Slight differences in the reference range values may exist with these new platforms (see charts on pages 6-9).

- Patients who receive care at multiple Vanderbilt Health locations may see both sets of reference values in their MyChart records, depending on which laboratory location processed their tests (see EPIC and MyChart trending examples on page 11).
- New reference ranges will be in place for some tests.
  - These tests will be exclusively performed at MetroCenter.
  - These labs have new reference range values (see charts on pages 2-5).
- High levels of circulating biotin in patients can interfere with some tests.
  - Roche assays use a biotin-streptavidin binding mechanism, which biotin interferes with.
  - Tests impacted are listed on page 10.
- Tumor marker tests will require patient re-baselining due to new reference ranges.
  - Impacted tumor marker tests are listed on page 16).
- Tests being run on the new platform require updated labeling and tube fill practices (see page 17).

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Tumor Marker Updates



Barcode Labeling for Roche

For more information, please visit the VUMC Laboratory Transformation website <u>VUMC.org/lab-transformation/</u> or call 5-LABS (5-5227).





#### Chemistry Tests with New Reference Intervals Test Name (LAB#) Changes/Impacts Previous Reference Range (Abbott) **New Reference Range (Roche)** Alpha Fetoprotein New reference intervals 0 Minutes - <13 Days =- 5000 - 105000 ng/mL 0 - < 14 days = 5000 - 105000 ng/mLNew lower reportable limit of 2.7 ng/mL (LAB559) 13 Days - < 30 Days = 300 - 60000 ng/mL $14 \, days - < 30 \, days = 300 - 60000 \, ng/mL$ 30 Days - <2 Months = 100 - 10000 ng/mL 1 months - <2 months = 100 - 10000 ng/mL (old method was 2 ng/mL) New tumor marker method 2 Months - <3 Months = 40 - 1000 ng/mL 2 months - <3 months = 40 - 1000 ng/mL 3 months - <4 months = 11 - 300 ng/mL Bias of ~10% (pos) 3 Months - <4 Months = 11 - 300 ng/mL 4 Months - <5 Months = 5 - 200 ng/mL May be falsely decreased in the 4 Months - <5 months = 5 - 200 ng/mL presence of biotin (180 ng/mL) 5 Months - < 6 Months = 0 - 90 ng/mL 5 months - < 6 months = 0 - 90 ng/mL 6 Months - <12 Months = 0 - 97 ng/mL 6 months - <12 months = 3.5 - 69 ng/mL 12 Months - <2 Years = 0 - 41 ng/mL 1 year - < 18 years = < 0.6 - 7 ng/mL2 Years - <3 Years = 0 - 12 ng/mL $\geq$ 18 years = 0 - 8.3 ng/mL $\geq$ 3 Years = 0 - 9.9 ng/mL Cancer Antigen 125 New reference intervals FEMALE 0 Minutes - 150 Years = 0 - 35 U/mL Pre-menopause = 5.4 - 127 U/mL New lower reportable limit of 2 U/mL (LAB155) Post-menopause = 4.1 - 47.9 U/mL (old method was 1.1 U/mL) New tumor marker method FEMALE 0 Minutes - 150 Years = 0 - 38.1 U/mL Bias of ~20% (neg) May be falsely decreased in the presence of biotin (35 ng/mL) C-Peptide (LAB521) New reference intervals 0 Minutes - 150 Years = 0.7 - 5.2 ng/mL 0 Minutes - 150 Years = 1.1 - 4.4 ng/mL New lower reportable limit of 0.15 ng/ mL (old method was 0.03 ng/mL) Bias of ~25% (pos) May be falsely decreased in the presence of biotin (60 ng/mL) Cystatin C (LAB3417) New reference intervals $0 - 1 = 1.5 - 2.85 \,\text{mg/dL}$ 0 days - <18 years = Reference interval not No pediatric ranges 1 month - < 5 months = 1.01 - 1.02 mg/dLestablished. Refer to estimated glomerular 5 months - <1 year = 0.75 - 1.50 mg/dLfiltration rate (eGFR) 1 year - < 2 years = 0.60 - 1.20 mg/dL2 years - < 18 years = 0.62 - 1.11 mg/dL18 years - < 49 years = 0.63 - 1.03 mg/dL18 years - 150 years = 0.51 - 1.05 mg/dL≥49 years = 0.67 - 1.21 mg/dL Dehydroepiandrosterone-0 minutes - <1 week = 108 - 607 mcg/dL New reference intervals 0 Minutes - <7 Days = 108 - 607 mcg/dL New lower reportable limit of 3 mcg/dL 7 Days - <30 Days = 32 - 431 mcg/dL 1 week - < 1 month = 31.6 - 431 mcg/dLSulfate (LAB524) (old method was 4.8 mcg/dL) 30 Days - <6 Months = 3 - 124 mcg/dL 1 month - <12 months = 3.4 - 124 mcg/dL Bias of ~10% 6 Months - < 3 Years = 0 - 33 mcg/dL1 year - < 4 years = 0.47 - 19.4 mcg/dLMay be falsely increased in the presence 3 Years - < 7 Years = 0 - 47 mcg/dL4 years - <10 years = 2.8 - 85.2 mcg/dL 7 Years - <10 Years = 5 - 115 mcg/dL of biotin (70 ng/mL) MALE 10 years - <15 years = 24.4 - 247 mcg/dL 10 Years - <15 Years = 22 - 332 mcg/dL 15 years - <20 years = 70.2 - 492 mcg/dL20 years - <25 years = 211 - 492 mcg/dL 15 Years - <20 Years = 88 - 483 mcg/dL 25 years - <35 years = 160 - 449 mcg/dL 20 Years - <30 Years = 280 - 640 mcg/dL 30 Years - <50 Years = 95 - 530 mcg/dL 35 years - <45 years = 88.9 - 427 mcg/dL 45 years - <55 years = 44.3 - 331 mcg/dL 50 Years - <60 Years = 70 - 310 mcg/dL 55 years - <65 years = 51.7 - 295 mcg/dL≥60 Years = 28 - 290 mcg/dL 65 years - <75 years = 33.6 - 249 mcg/dL ≥75 years = 16.2 - 123 mcg/dL 10 Years - <15 Years = 22 - 255 mcg/dL 15 Years - <30 Years = 63 - 380 mcg/dL 30 Years - <50 Years = 32 - 270 mcg/dL 10 years - <15 years = 33.9 - 280 mcg/dL 50 Years - <60 Years = 26 - 200 mcg/dL 15 years - <20 years = 65.1 - 368 mcg/dL≥60 Years = 10 - 130 mcg/dL 20 years - <25 years = 148 - 407 mcg/dL 25 years - <35 years = 98.8 - 340 mcg/dL 35 years - < 45 years = 60.9 - 337 mcg/dL45 years - <55 years = 35.4 - 256 mcg/dL 55 years - <65 years = 18.9 - 205 mcg/dL 65 years - < 75 years = 9.4 - 246 mcg/dL≥75 years = 12 - 154 mcg/dL



Chemistry Tests with New Reference Intervals			
Test Name (LAB#)	Changes/Impacts	Previous Reference Range (Abbott)	New Reference Range (Roche)
Estradiol (LAB523)	New reference intervals New lower reportable limit of 25 pg/mL (old method was 24 pg/mL) May be falsely increased in the presence of biotin (36 ng/mL)	O Minutes - <15 Days = Reference interval not established.  15 Days - <12 Months = 0 - 24 pg/mL  MALE  12 Months - <11 Years = 0 - 13 pg/mL  11 Years - <15 Years = 0 - 28 pg/mL  15 Years - <19 Years = 0 - 38 pg/mL  ≥19 Years = 11 - 44 pg/mL  FEMALE  12 Months - <9 Years = 0 - 10 pg/mL  9 Years - <12 Years = 0 - 94 pg/mL  12 Years - <14 Years = 11 - 172 pg/mL	0 Minutes - <1 month = 2.5 - 96 pg/mL 1 month - <10 years = 0 - 4.9 pg/mL 10 years - <14 years = 0 - 4.9 pg/mL  MALE 10 years - <18 years = 4.9 - 36.5 pg/mL ≥18 years = 11.3 - 43.2 pg/mL  FEMALE 14 years - <19 years = 14.6 - 249 pg/mL ≥19 years = See menstrual phase information below Follicular = 30.9 - 90.4 pg/mL Ovulation = 60.4 - 533 pg/mL Luteal = 60.3 - 232 pg/mL Post-menopause = <5 - 138 pg/mL
Folate (LAB69)	New reference intervals New lower reportable limit of 2 ng/mL (old method was 2.2 ng/mL) May be falsely increased in the presence of biotin (21 ng/mL)	0 Minutes - 150 Years = 5.9 - 24.8 ng/mL	0 Minutes - <7 years = ≥7.6 7 years - <12 years = ≥16.7 ≥12 years = ≥4.6
Follicle Stimulating Hormone (LAB86)	New reference intervals New lower reportable limit of 1 mIU/mL (old method was 0.2 mIU/mL) Bias of ~10% (pos)  Page 10 miles of	MALE 1 - 11 months = 0.1 - 2.4 mIU/mL 1 - 9 years = 0 - 1.6 mIU/mL 10 - 18 years = 0.4 - 5.1 mIU/mL 19 - 150 years = 1 - 12.0  FEMALE 1 - 11 months = 0.5 - 11 mIU/mL 1 - 10 years = 0.4 - 5.5 mIU/mL 11 - 14 years = 0.3 - 7.8 mIU/mL 15 - 150 years = see interpretive table below Normal Menstruating Females Follicular = 3.0 - 8.0 mIU/mL Ovulation = 2.5 - 17.0 mIU/mL Luteal = 1.3 - 5.5 mIU/mL Post-menopause = 25 - 135 mIU/mL	MALE 0 minutes - <1 year = 0.1 - 3.2 mIU/mL 1 year - <9 years = 0.2 - 2.1 mIU/mL 9 years - <12 years = 0.4 - 4.2 mIU/mL 12 years - <18 years = 0.9 - 7.1 mIU/mL ≥18 years = 1.5 - 12.4 mIU/mL  FEMALE 0 minutes - <1 year = 1.6 - 19 mIU/mL 1 year - <9 years = 0.7 - 5.8 mIU/mL 9 years - <12 years = 0.5 - 7.6 mIU/mL 12 years - <18 years = 0.9 - 9.1 mIU/mL ≥18 years = See menstrual phase information below Follicular = 3.5 - 12.5 mIU/mL Ovulation = 4.7 - 21.5 mIU/mL Luteal = 1.7 - 7.7 mIU/mL Post-menopause = 25.8 - 134.8 mIU/mL
Immunoglobulin A (LAB73)	New reference intervals     New lower reportable limit of 10 mg/dL (old method was 5 mg/dL)	0 Minutes - <3 Months = 1 - 34 mg/DL 3 Months - <1 Years = 8 - 91 mg/dL 1 Years - <3 Years = 0 - 90 mg/dL 3 Years - <6 Years = 30 - 150 mg/dL 6 Years - <14 Years = 50 - 220 mg/dL 14 Years - <19 Years = 50 - 290 mg/dL MALE 19 Years - <60 Years = 63 - 484 mg/dL FEMALE 19 Years - <60 Years = 65 - 421 mg/dL MALE ≥60 Years = 101 - 645 mg/dL FEMALE ≥60 Years = 69 - 517 mg/dL	0 minutes - <1 year = 0 - 10 mg/dL 1 year - <3 years = 0 - 80 mg/dL 3 years - <6 years = 10 - 140 mg/dL 6 years - <14 years = 30 - 220 mg/dL 14 years - <18 years = 40 - 290 mg/dL ≥18 years = 70 - 400 mg/dL
Immunoglobulin G (LAB71)	New reference intervals     New lower reportable limit of 300 mg/dL (old method was 109 mg/dL)	0 Minutes - <15 Days = 320 - 1400 mg/dL 15 Days - <1 Years = 110 - 700 mg/dL 1 Years - <4 Years = 320 - 1150 mg/dL 4 Years - <10 Years = 540 - 1360 mg/dL 10 Years - <19 Years = 660 - 1530 mg/dL MALE 19 Years - 80 Years = 540 - 1822 mg/dL FEMALE 19 Years - 80 years = 552 - 1631 mg/dL	0 minutes - <15 days = 320 - 1210 mg/dL 15 days - <1 year = 150 - 630 mg/dL 1 year - <4 years = 320 - 990 mg/dL 4 years - <10 years = 500 - 1170 mg/dL 10 years - <18 years = 600 - 1310 mg/dL ≥18 years = 700 - 1600 mg/dL



#### Chemistry Tests with New Reference Intervals Test Name (LAB#) Changes/Impacts Previous Reference Range (Abbott) **New Reference Range (Roche)** Immunoglobulin M New reference intervals 0 Minutes - <15 Days = 10 - 40 mg/dL 0 minutes - <15 days = 0 - 30 mg/dL15 Days - <13 Weeks = 10 - 70 mg/dL New lower reportable limit of 4 mg/dL $15 \, \text{days} - < 13 \, \text{weeks} = 10 - 70 \, \text{mg/dL}$ (LAB72) 13 Weeks - <1 Years = 20 - 90 mg/dL 13 weeks - <1 year = 10 - 80 mg/dL (old method was 5 mg/dL) MALE 1 Years - <19 Years = 40 - 150 mg/dL MALE 1 years - <18 years = 50 - 180 mg/dL FEMALE 1 Years - <19 Years = 50 - 190 mg/dL FEMALE 1 years - <18 years = 40 - 140 mg/dL MALE ≥19 Years = 22 - 240 mg/dL $\geq$ 18 years = 40 - 230 mg/dL FEMALE ≥19 Years = 33 - 293 mg/dL **Luteinizing Hormone** O Minutes - <3 Months = Reference interval not • New reference intervals 0 days - <18 years = Reference interval not (LAB87) No pediatric ranges established. established. New lower reportable limit of 1 mIU/mL FEMALE ≥18 Years = See menstrual phase 3 Months - <1 Years = 0 - 2.9 mIU/mL (old method was 0.2 mIU/mL) information below Bias >50% proportional (pos) 1 Years - <10 Years = 0 - 0.5 mIU/mL Follicular = 2.4 - 12.6 mIU/mL Ovulation = 14 - 95.5 mlU/mL May be falsely decreased in the 10 Years - <13 Years = 0 - 4.3 mIU/mL presence of biotin (50 ng/mL) 13 Years - <15 Years = 0 - 6.4 mIU/mL Luteal = 1 - 11.4 mIU/mL MALE ≥ 15 Years = 0.6 - 12 mIU/mL Post-menopause = 7.7 - 58.5 mIU/mL FEMALE ≥ 15 Years = See menstrual phase MALE ≥18 Years = 1.7 - 8.6 mIU/mL information below Follicular = 1.8 - 11.8 mIU/mL Ovulation = 7.0 - 89 mIU/mL Luteal = 0.5 - 14 mIU/mL Post-menopause: 5.0 - 62 mIU/mL O Minutes - <1 Months = Reference interval not Progesterone (LAB529) New reference intervals 0 Minutes - < 1 month = 0.3 - 242 ng/mLNew lower reportable limit of 0.2 ng/mL established. (old method was 0.5 ng/mL) Bias of ~15% (pos) 1 Months - <1 Years = 0 - 0.7 ng/mL 1 month - < 12 years = 0.3 - 0.9 ng/mL May be falsely increased in the presence 1 Years - <10 Years = 0 - 0.3 ng/mL 12 years - < 19 years = 0.3 - 12 ng/mL of biotin (30 ng/mL) ≥19 years (Female) = See menstrual phase **FFMALF** information below 10 Years - < 14 Years = 0.1 - 0.8 ng/mLFollicular = <0.05 - 0.193 ng/mL ≥14 Years = See menstrual phase information Ovulation = 0.055 - 4.14 ng/mL Luteal = 4.11 - 14.5 ng/mL Follicular = < 0.3 ng/mL, Post-menopause = < 0.05 - 0.126 ng/mL Luteal = 1.2 - 15.9 ng/mL, Post-menopause = <0.2 ng/mL 1 month - <18 years = 0.3 - 0.9 ng/mL $\geq$ 18 years = 0 - 0.2 ng/mL 10 Years - <15 Years = 0.1 - 0.8 ng/mL 15 Years - <18 Years = 0.1 - 0.6 ng/mL $\geq$ 18 Years = 0 - 0.2 ng/mL Prolactin (LAB531) New reference intervals O Minutes - <1 Months = Reference interval not 0 Minutes - <1 Months = 1.1 - 470 ng/mL Bias of ~15% (pos) established. 1 Months - <12 Months = 5.2 - 60 ng/mL May be falsely decreased in the 1 Years - <18 Years = 3 - 25 ng/mL presence of biotin (40 ng/mL) 1 Months - <1 Years = 6 - 114 ng/mL MALE ≥18 Years = 4.0 - 15.2 ng/mL 1 Years - <18 Years = 4 - 23 ng/mL FEMALE ≥18 Years = 4.8 - 23.3 ng/mL MALE ≥18 Years = 3 - 20 ng/mL

FEMALE ≥18 Years = 3 - 27 ng/mL



#### Chemistry Tests with New Reference Intervals Test Name (LAB#) **Changes/Impacts Previous Reference Range (Abbott) New Reference Range (Roche) Testosterone Total** New reference intervals O Days - <4 Days = Reference interval not MALE (LAB124) New lower reportable limit of 12 ng/mL 0 - 6 Months = 5.8 - 548 ng/dLestablished. 6 Months - <11 Years = 2.9 - N/A (old method was 4.4 ng/mL) MALE 11 Years - <15 Years = 2.9 - 563 ng/dL 4 Days - <6 Months = 8.7 - 298.9 ng/dL 15 Years - <18 Years = 49 - 769 ng/dL 6 Months - <9 Years = 0 - 35.7 ng/dL ≥Years - <50 Years = 249 - 836 ng/dL 9 Years - <11 Years = 0 - 23.3 ng/dL ≥50 Years = 193 - 740 ng/dL 11 Years - <14 Years = 0 - 444.4 ng/dL 14 Years - <16 Years = 36 - 632.3 ng/dL **FEMALE** 0 - <6 Months = 2.9 - 346 ng/dL 16 Years - <19 Years = 147.8 - 794 ng/dL 19 Years - <50 Years = 187.2 - 950.3 ng/dL 6 Months - <11 Years = 2.9 - N/A ≥50 Years = 178.4 - 986.7 ng/dL 11 Years - <18 Years = 2.9 - 52 ng/dL ≥18 Years - <50 Years = 8.4 - 48.1 ng/dL ≥50 Years = 2.9 - 40.8 ng/dL 4 Days - <9 Years = 1.2 - 62 ng/dL 9 Years - <11 Years = 0 - 28.2 ng/dL 11 Years - <14 Years = 0 - 44.4 ng/dL 14 Years - <19 Years = 14.1 - 49 ng/dL 19 Years - <50 Years = 12.3 - 58.5 ng/dL ≥50 Years = 9.7 - 986.7 ng/dL Vitamin B12 (LAB67) 0 Minutes - 150 Years = 213 - 816 pg/mL 0 - <18 Years = Reference interval not established. New reference intervals No pediatric ranges New lower reportable limit of 150 pg/ ≥18 Years = 232 - 1245 pg/mL mL (old method was 148 pg/mL) • May be falsely increased in the presence of biotin (50 ng/mL)

All IP testing from the downtown campus and all STAT testing from ambulatory clinics within a 1-mile radius of downtown campus will be performed at TVC (i.e., on the Abbott platform). All ambulatory testing >1 mile from the main campus and all routine testing from the ambulatory centers within a mile of downtown campus will be sent to MetroCenter (i.e., performed on the new Roche platform).



Chemistry Tests with Two Reference Intervals			
Test Name	Changes/Impacts	Abbott Reference Range (Other Vanderbilt Lab Locations)	Roche Reference Range (MetroCenter Location)
Albumin (LAB45)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 - <15 days = 3.3 - 4.5 g/dL 15 days - <1 Years = 2.8 - 4.7 g/dL 1 Year - <8 Years = 3.8 - 4.7 g/dL 8 Years - <15 Years = 4.1 - 4.8 g/dL 15 Years - <19 Years = 4 - 5.1 g/dL 19 Years - <60 Years = 3.5 - 5.2 g/dL 60 Years - <90 Years = 3.2 - 4.6 g/dL >90 Years = 2.9 - 4.5 g/dL	0 - <15 days = 3.3 - 4.5 g/dL 15 days - <1 years = 3.1 - 5 g/dL 1 year - <8 years = 4 - 4.9 g/dL 8 years - <15 years = 4.2 - 5.1 g/dL MALE 15 years - <18 years = 4.3 - 5.3 g/dL FEMALE 15 years - <18 years = 4.0 - 5.3 g/dL ≥18 years = 3.9 - 4.9 g/dL
Alkaline Phosphatase (LAB112)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete Bias on higher values -15% (pos) for Roche  Two reference intervals, one for each platform (Abbott and Roche), until transition complete Two reference intervals, one for each platform (Abbott and Roche), until transition (Possible Possible Po	0 - <15 days = 90 - 273 U/L 15 days - <1 Year = 134 - 518 U/L 1 Year - <10 Years = 156 - 369 U/L 10 Years - <13 Years = 141 - 460 U/L ≥19 Years = 40 - 150 U/L  MALE 13 Years - <15 Years = 127 - 517 U/L 15 Years - <17 Years = 89 - 365 U/L 17 Years - <19 Years = 54 - 128 U/L 15 Years - <17 Years = 62 - 280 U/L 15 Years - <17 Years = 54 - 128 U/L 15 Years - <17 Years = 54 - 128 U/L 17 Years - <19 Years = 59 - 164 U/L	0 - <15 days = 83 - 248 U/L 15 days - <1 year = 122 - 469 U/L 10 years - <13 years = 129 - 417 U/L  MALE 13 years - <15 years = 116 - 468 U/L 15 years - <17 years = 82 - 331 U/L 17 years - <18 years = 55 - 149 U/L ≥18 years = 40 - 129 U/L  FEMALE 13 years - <15 years = 57 - 254 U/L 15 years - <17 years = 50 - 117 U/L 17 years - <18 years = 45 - 87 U/L ≥18 years = 35 - 104 U/L
Alanine Aminotransferase (LAB132)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete Bias on higher values ~25% (pos) for Roche  Two reference intervals, one for each platform (Abbott) and Roche  Two reference intervals, one for each platform (Abbott) and Roche  Two reference intervals, one for each platform (Abbott) and Roche  Two reference intervals, one for each platform (Abbott) and Roche), until transition (Abbott) and Roche) and Roche).	0 - <1 Year = 5 - 51 U/L 1 Year - <13 Years = 9 - 25 U/L 13 Years - <19 Years = 8 - 24 U/L ≥19 Years = 0 - 55 U/L	0 - <1 year = 0 - 25 U/L 1 year - <13 years = 0 - 19 U/L MALE 13 years - <18 years = 0 - 18 U/L FEMALE 13 years - <18 years = 0 - 17 U/L MALE ≥18 years = 10 - 50 U/L FEMALE ≥18 years = 10 - 35 U/L
Aspartate Aminotransferase (LAB131)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete Bias on higher values ~25% (pos) for Roche	0 - <15 days = 32 - 162 U/L 15 days - <1 Year = 20 - 67 U/L 1 Year - <7 Years = 21 - 44 U/L 7 Years - <12 Years = 18 - 36 U/L 12 Years - <19 Years = 13 - 35 U/L ≥19 Years = 5 - 40 U/L	0 - <15 days = 40 - 175 U/L 15 days - <1 year = 28 - 177 U/L 1 year - <7 years = 29 - 53 U/L 7 years - <12 years = 26 - 45 U/L MALE 12 years - <18 years = 22 - 44 U/L FEMALE 12 years - <18 years = 21 - 34 U/L MALE ≥18 years = 10 - 50 U/L MALE ≥18 years = 10 - 35 U/L
Bilirubin, Total (LAB50)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete Bias on higher values ~10% (pos) for Roche	0 Minutes - <1 Days = 0.2 - 6 mg/dL 1 Days - <2 Days = 0.2 - 10 mg/dL 2 Days - <5 Days = 0.2 - 12 mg/dL 5 Days - <15 Days = 0.2 - 10 mg/dL 15 Days - <30 Days = 0.1 - 0.7 mg/dL 30 Days - <1 Years = 0.1 - 0.7 mg/dL 1 Years - <9 Years = 0.1 - 0.4 mg/dL 9 Years - <12 Years = 0.1 - 0.6 mg/dL 12 Years - <15 Years = 0.1 - 0.8 mg/dL ≥19 Years = 0.2 - 1.2 mg/dL	0 - <24 hours = 0 - 7.9 mg/dL 24 hours - <48 hours = 0 - 12.9 mg/dL 48 hours - <84 hours = 0 - 16.9 mg/dL 84 hours - <15 days = 0 - 14.6 mg/dL 15 days - <1 year = 0 - 0.6 mg/dL 1 year - <9 years = 0 - 0.3 mg/dL 9 years - <12 years = 0 - 0.5 mg/dL 12 years - <15 years = 0 - 0.6 mg/dL 15 years - <18 years = 0 - 0.7 mg/dL ≥18 years = 0 - 1.2 mg/dL
Bilirubin, Direct (LAB52)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 - <15 days = 0.3 - 0.7 mg/dL 15 days - <1 Year = 0.1 - 0.3 mg/dL 1 Year - <9 Years = 0.1 - 0.2 mg/dL 9 Years - <13 Years = 0.1 - 0.3 mg/dL 13 Years - <19 Years = 0.1 - 0.4 mg/dL ≥19 Years = 0 - 0.5 mg/dL	0 - <15 days = 0.3 - 0.5 mg/dL 15 days - <1 year = 0 - 0.2 mg/dL 1 year - <9 years = 0 - 0.1 mg/dL 9 years - <13 years = 0 - 0.2 mg/dL MALE 13 years - <18 years = 0.1 - 0.3 mg/dL FEMALE 13 years - <18 years = 0 - 0.3 mg/dL ≥18 years = 0 - 0.3 mg/dL



Chemistry Tests with Two Reference Intervals				
Test Name	Changes/Impacts	Abbott Reference Range (Other Vanderbilt Lab Locations)	Roche Reference Range (MetroCenter Location)	
Urea Nitrogen (LAB140)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 Days - <15 Days = 3 - 22 mg/dL 15 Days - <1 Year = 4 - 17 mg/dL 1 Year - <10 Years = 9 - 22 mg/dL 10 Years - <19 Years = 7 - 20 mg/dL 19 Years - <50 Years = 7 - 21 mg/dL ≥50 Years = 8 - 26 mg/dL	0 - <15 days = 3 - 22 mg/dL 15 days - <1 year = 4 - 16 mg/dL 1 year - <10 years = 9 - 21 mg/dL MALE 10 years - <19 years = 7 - 20 mg/dL FEMALE 10 years - <19 years = 7 - 18 mg/dL 19 years - <60 years = 6 - 20 mg/dL 60 years - <90 years = 8 - 23 mg/dL ≥90 years = Reference interval not established.	
Calcium (LAB53)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete Bias -10% (pos) for Roche	0 Minutes - <10 Days = 7.6 - 10.4 mg/dL 10 Days - <2 Years = 9 - 11 mg/dL 2 Years - <12 Years = 8.8 - 10.8 mg/dL ≥12 Years = 8.4 - 10.5 mg/dL	0 - <10 days = 7.6 - 10.4 mg/dL 10 days - <2 years = 9 - 11 mg/dL 2 years - <12 years = 8.8 - 10.8 mg/dL 12 years - <18 years = 8.4 - 10.2 mg/dL 18 years - <60 years = 8.60 - 10 mg/dL 60 years - <90 years = 8.8 - 10.2 mg/dL ≥90 years = 8.2 - 9.6 mg/dL	
Carbon Dioxide (LAB55)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 Minutes - <15 Days = 5 - 20 mmol/L 15 Days - <1 Year = 10 - 24 mmol/L 1 Years - <5 Years = 14 - 24 mmol/L 5 Years - <15 Years = 17 - 26 mmol/L 15 Years - <19 Years = 17 - 28 mmol/L 19 Years - <60 Years = 22 - 29 mmol/L ≥60 Years = 23 - 31 mmol/L	0 - <15 days = 5 - 20 mmol/L 15 days - <1 year = 10 - 24 mmol/L 1 year - <5 years = 14 - 24 mmol/L 5 years - <15 years = 17 - 26 mmol/L 15 years - <18 years = 17 - 28 mmol/L ≥18 years = 22 - 29 mmol/L	
Creatine Kinase (LAB62)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	MALE 0 minutes - 150 years = 30 - 200 U/L FEMALE 0 minutes - 150 years = 29 - 168 U/L	O - <6 years = Reference interval not established  MALE 6 years - <12 years = 150 - 499 U/L 12 years - <18 years = 94 - 499 U/L ≥18 years = 39 - 308 U/L  FEMALE 6 years - <8 years = 134 - 391 U/L 8 years - <15 years = 91 - 391 U/L 15 years - <18 years = 53 - 269 U/L ≥18 years = 26 - 192 U/L	
Creatinine (LAB66)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 Minutes - <15 Days = 0.42 - 1.05 mg/dL 15 Days - <1 Years = 0.31 - 0.53 mg/dL 1 Years - <4 Years = 0.39 - 0.55 mg/dL 4 Years - <7 Years = 0.44 - 0.65 mg/dL 7 Years - <12 Years = 0.52 - 0.63 mg/dL 12 Years - <15 Years = 0.57 - 0.8 mg/dL  MALE 15 Years - <17 Years = 0.65 - 1.04 mg/dL 17 Years - <19 Years = 0.69 - 1.1 mg/dL ≥19 Years = 0.72 - 1.25 mg/dL  FEMALE 15 Years - <17 Years = 0.59 - 0.86 mg/dL 17 Years - <19 Years = 0.6 - 0.88 mg/dL ≥19 Years = 0.57 - 1.11 mg/dL	0 - <2 months = 0.24 - 0.85 mg/dL 2 months - <12 months = 0.17 - 0.42 mg/dL 1 year - <3 years = 0.24 - 0.41 mg/dL 3 years - <5 years = 0.31 - 0.47 mg/dL 5 years - <7 years = 0.32 - 0.59 mg/dL 7 years - <9 years = 0.40 - 0.60 mg/dL 9 years - <11 years = 0.39 - 0.73 mg/dL 11 years - <13 years = 0.53 - 0.79 mg/dL 13 years - <15 years = 0.57 - 0.87 mg/dL MALE ≥15 years = 0.7 - 1.2 mg/dL FEMALE ≥15 years = 0.5 - 0.9 mg/dL	



Chemistry Tests with Two Reference Intervals				
Test Name	Changes/Impacts	Abbott Reference Range (Other Vanderbilt Lab Locations)	Roche Reference Range (MetroCenter Location)	
Ferritin (LAB68)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete May be falsely decreased in the presence of biotin (50 ng/mL) for Roche	MALE 0 minutes - 150 years = 24 - 336 ng/mL FEMALE 0 minutes - 150 years = 15 - 204 ng/mL	0 - <1 month = 150 - 973 ng/mL 1 month - <6 months = 8 - 580 ng/mL 6 months - <15 years = 14 - 101 ng/mL  MALE 15 years - <19 years = 21 - 173 ng/mL 19 years - <60 years = 30 - 400 ng/mL ≥60 years = 31 - 409 ng/mL  FEMALE 15 years - <19 years = 34 - 114 ng/mL 19 years - <60 years = 15 - 150 ng/mL ≥60 years = 11 - 328 ng/mL	
Glucose CSF (LAB185)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 minutes - 150 years = 45 - 75 mg/dL	0 - <18 years = 60 - 80 mg/dL 18 years - 150 years = 40 - 70 mg/dL	
Haptoglobin (LAB89)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 Minutes - <15 Days = 0 - 10 mg/dL 15 Days - <1 Years = 7 - 221 mg/dL 1 Years - <12 Years = 7 - 163 mg/dL 12 Years - <19 Years = 7 - 179 mg/dL 19 Years - <60 Years = 14 - 258 mg/dL ≥60 Years = 40 - 273 mg/dL	0 - <15 days = 0 - 12 mg/dL 15 days - <1 year = 0 - 238 mg/dL 1 year - <12 years = 0 - 176 mg/dL 12 years - <18 years = 0 - 193 mg/dL ≥18 years = 30 - 200 mg/dL	
Lactate Dehydrogenase (LAB96)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 Minutes - <15 Days = 309 - 1222 IU/L 15 Days - <1 Years = 163 - 452 IU/L 1 Years - <10 Years = 192 - 321 IU/L 10 Years - <15 Years = 157 - 283 IU/L 15 Years - <19 Years = 130 - 250 IU/L ≥19 Years = 125 - 220 IU/L	0 - <30 days = 130 - 700 IU/L 1 month - <5 years = 130 - 400 IU/L 5 years - <12 years = 100 - 300 IU/L 12 years - 150 years = 100 - 250 IU/L	
Magnesium (LAB103)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	0 Minutes - <5 Months = 1.5 - 2.2 mg/dL 5 Months - <6 Years = 1.7 - 2.3 mg/dL 6 Years - <20 Years = 1.7 - 2.2 mg/dL ≥20 Years = 1.6 - 2.6 mg/dL	0 - <5 months = 1.5 - 2.2 mg/dL 5 months - <6 years = 1.7 - 2.3 mg/dL 6 years - <12 years = 1.7 - 2.1 mg/dL 12 years - <20 years = 1.7 - 2.2 mg/dL ≥20 years = 1.6 - 2.6 mg/dL	
Phosphorus (LAB113)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	O Minutes - <15 Days = 5.6 - 10.5 mg/dL 15 Days - <1 Years = 4.8 - 8.4 mg/dL 1 Years - <5 Years = 4.3 - 6.8 mg/dL 5 Years - <13 Years = 4.1 - 5.9 mg/dL 13 Years - <16 Years = 3.2 - 6.2 mg/dL 16 Years - <19 Years = 2.9 - 5 mg/dL ≥19 Years = 2.3 - 4.7 mg/dL	MALE 0 - <30 days = 3.6 - 6.9 mg/dL 1 month - <12 months = 3.5 - 6.6 mg/dL 1 year - <4 years = 3.1 - 6 mg/dL 4 years - <7 years = 3.3 - 5.6 mg/dL 7 years - <10 years = 3 - 5.4 mg/dL 10 years - <13 years = 3.2 - 5.7 mg/dL 13 years - <16 years = 2.9 - 5.1 mg/dL 16 years - <18 years = 2.7 - 4.9 mg/dL FEMALE 0 - <30 days = 4.3 - 7.7 mg/dL 1 month - <12 months = 3.7 - 6.5 mg/dL 1 year - <4 years = 3.4 - 6 mg/dL 4 years - <7 years = 3.2 - 5.5 mg/dL 7 years - <10 years = 3.1 - 5.5 mg/dL 10 years - <13 years = 3.3 - 5.3 mg/dL 13 years - <16 years = 2.8 - 4.8 mg/dL ≥18 years = 2.5 - 4.5 mg/dL ≥18 years = 2.5 - 4.5 mg/dL	
Protein CSF (LAB195)	Two reference intervals, one for each platform (Abbott and Roche), until transition complete	Premature 0 - <1 month = 15 - 130 mg/dL Newborn 0 - <1 month = 40 - 120 mg/dL 1 month - 150 years = 15 - 40 mg/dL	0 - <1 month = 40 - 120 mg/dL <1 month: Premature range is 15 - 130 mg/dL 1 month - <18 years = 15 - 40 mg/dL ≥18 years = 15 - 45 mg/dL	



#### Chemistry Tests with Two Reference Intervals **Abbott Reference Range Roche Reference Range Test Name** Changes/Impacts (Other Vanderbilt Lab Locations) (MetroCenter Location) Total Protein (LAB118) Two reference intervals, one for each 0 Minutes - <15 Days = 5.3 - 8.3 g/dL 0 - < 15 days = 5.1 - 8.0 g/dL15 Days - <1 Years = 4.4 - 7.1 g/dL 15 days - < 1 year = 4.3 - 6.9 g/dLplatform (Abbott and Roche), until 1 Years - <6 Years = 6.1 - 7.5 g/dL1 year - < 6 years = 5.9 - 7.3 g/dLtransition complete 6 years = <9 years = 6.2 - 7.5 g/dL6 Years - <9 Years = 6.4 - 7.7 g/dL 9 Years - <19 Years = 6.5 - 8.1 g/dL 9 years - <18 years = 6.3 - 7.8 g/dL $\geq$ 19 Years = 6 - 8.3 g/dL $\geq$ 18 years = 6.6 - 8.7 g/dL 0 Minutes - <9 Weeks = 104 - 224 mg/dL Transferrin (LAB133) 0 - < 9 weeks = 111 - 243 mg/dL • Two reference intervals, one for each platform (Abbott and Roche), until 9 Weeks - <1 Years = $107 - 324 \,\text{mg/dL}$ 9 weeks - <1 year = 115 - 352 mg/dL 1 year - <18 years = 238 - 366 mg/dL 1 Years - <19 Years = 220 - 337 mg/dL transition complete 19 Years - <60 Years = 174 - 382 mg/dL $\geq$ 18 years = 200 - 360 mg/dL ≥60 Years = 163 - 630 mg/dL 0 Minutes - <15 Days = 2.8 - 12.7 mg/dL 0 - < 15 days = 2.7 - 12.6 mg/dLUric Acid (LAB141) • Two reference intervals, one for each platform (Abbott and Roche), until 15 Days - < 1 Years = 1.6 - 6.3 mg/dL15 days - < 1 year = 1.5 - 6.2 mg/dLtransition complete 1 Years - <12 Years = 1.8 - 4.9 mg/dL 1 year - <12 years = 1.7 - 4.7 mg/dL MALE 12 Years - <19 Years = 2.6 - 7.6 mg/dL MALE 12 years - <18 years = 2.5 - 7.5 mg/dL FEMALE 12 Years - <19 Years = 2.6 - 5.9 mg/dL FEMALE 12 years - <18 years = 2.5 - 5.7 mg/dL MALE ≥19 Years = 3.5 - 7.2 mg/dL MALE $\geq$ 18 years = 3.4 - 7 mg/dL FEMALE ≥19 Years = 2.6 - 6 mg/dL FEMALE ≥18 years = 2.4 - 5.7 mg/dL



### Potential Biotin Impact on Roche Immunoassay Tests

### **Biotin Impact on Test Accuracy**

High levels of circulating biotin can potentially interfere with Roche immunoassays due to their component biotin-streptavidin binding mechanism. Biotin levels associated with normal dietary intake and multivitamin use are insufficient to cause assay interference. However, very high doses may be prescribed as a therapy for multiple sclerosis (300 mg/day (1) as well as biotinidase deficiency (5-10 mg/day) and holocarboxylase synthetase deficiency (30-40 mg/day) (2). Doses > 5 mg/day are also present in increasingly popular over-the-counter supplements for hair and nail strength. Numerous reports of erroneous lab results have been linked to supraphysiological biotin intake (3,4).

Samples should **not** be collected until at least 8 hours post-dose in patients receiving > 5 mg biotin per day, with interference thresholds ranging from 21 to 100 ng/mL (see table below).

Tests that May Be Falsely Increased due to Biotin	LAB#	Tests that May Be Falsely Decreased due to Biotin	LAB#
Vitamin B12 (50 ng/mL)	LAB67	Prolactin (40 ng/mL)	LAB531
Progesterone (30 ng/mL)	LAB529	Luteinizing Hormone (50 ng/mL)	LAB87
Folate (21 ng/mL)	LAB69	C-Peptide (60 ng/mL)	LAB521
Ferritin (50 ng/mL)	LAB68	Cancer Antigen 125 (35 ng/mL)	LAB155
Estradiol (36 ng/mL)	LAB523	Carcinoembryonic Antigen (70 ng/mL)	LAB57
Dehydroepiandrosterone Sulfate (70 ng/mL)	LAB524		

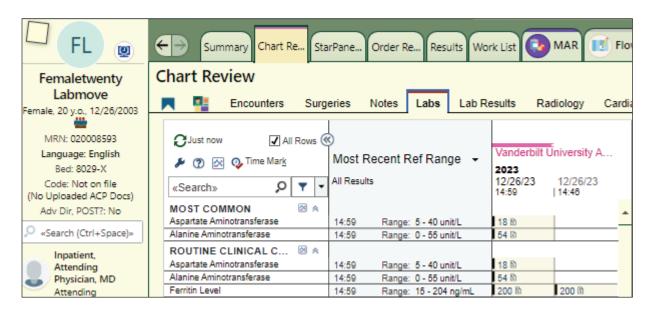
### References

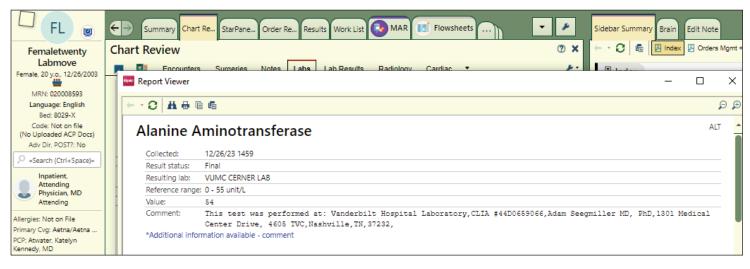
- 1. Tourbah A. et al. Md1003 (high-dose biotin) for the treatment of progressive multiple sclerosis: a randomized, double-blind, placebo-controlled study. Mult Scler 2016; 22:1719–31.
- 2. Avery G. Biotin interference in immunoassay: a review for the laboratory scientist. Annals of Clinical Biochemistry. 2019;56(4):424-430. doi:10.1177/0004563219842231.
- 3. Li D, et al. AACC guidance document on biotin interference in laboratory tests. J Appl Lab Med January 13, 2020, as doi:10.1373/10.1093/jalm/ifz010.
- 4. Motte J, Gold R. High-dose biotin in multiple sclerosis: the end of the road. Lancet Neurol. 2020 Dec;19(12):965-966. doi: 10.1016/S1474-4422(20)30353-7.
- 5. Sanders A, et al. Biotin immunoassay interference: A UK-based prevalence study. Annals of Clinical Biochemistry. 2021;58(1):66-69. doi:10.1177/0004563220961759.
- 6. Katzman BM, et al. Prevalence of biotin supplement usage in outpatients and plasma biotin concentrations in patients presenting to the emergency department. Clin Biochem. 2018 Sep;60:11-16. doi: 10.1016/j.clinbiochem.2018.07.004.
- 7. Trambas CM, et al. Further assessment of the prevalence of biotin supplementation and its impact on risk. Clin Biochem. 2019 Mar;65:64-65. doi: 10.1016/j.clinbiochem.2019.01.004.
- 8. IJpelaar A, Beijers A, van Daal H, van den Ouweland JMW. Prevalence of detectable biotin in The Netherlands in relation to risk on immunoassay interference. Clin Biochem. 2020 Sep;83:78-80. doi: 10.1016/j.clinbiochem.2020.05.009.

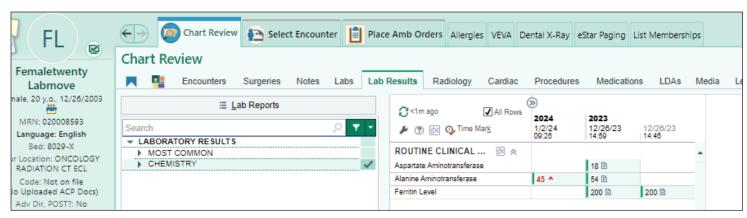


### Reference Range Change Example in Epic

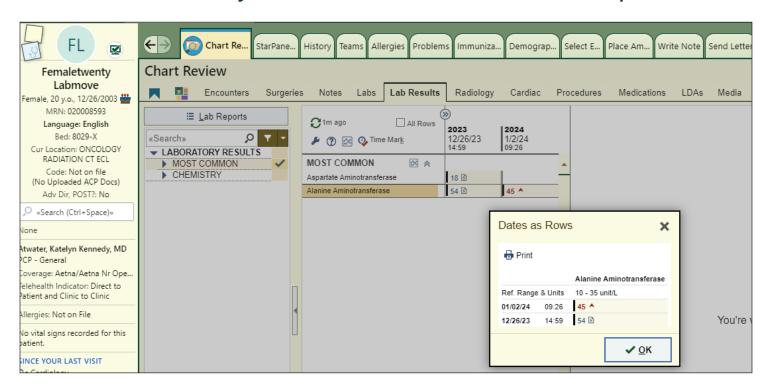
Example: ALT Test Female, 20 years old. MRN 20008593 Abbott Result 54 on 12/26/2023 and Roche result 45 on 01/02/2024.

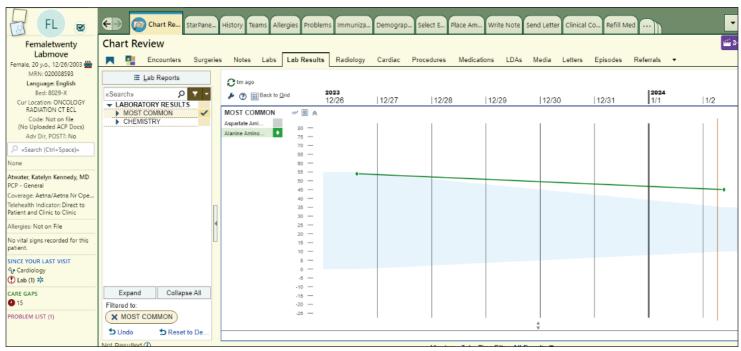




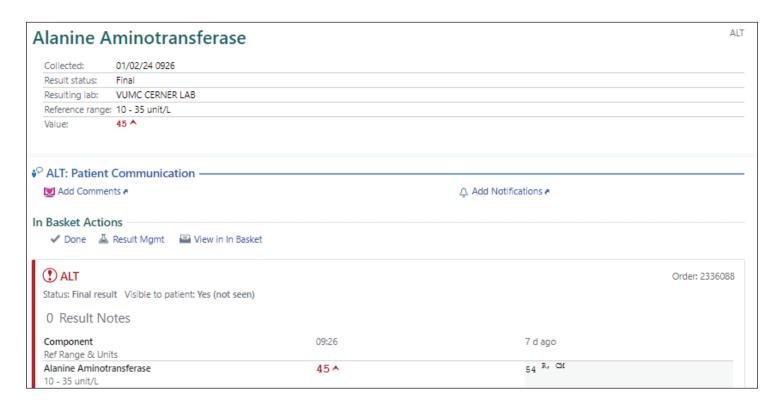






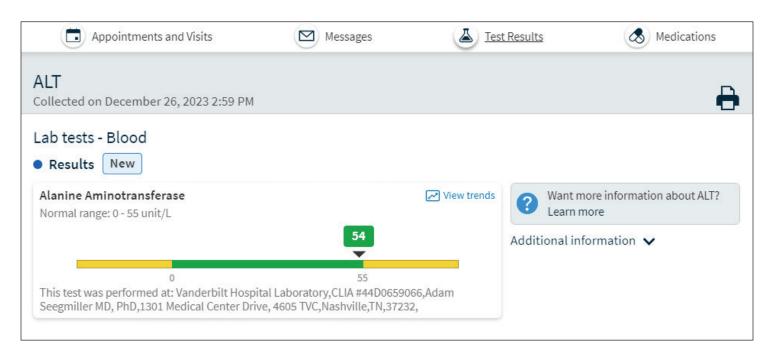


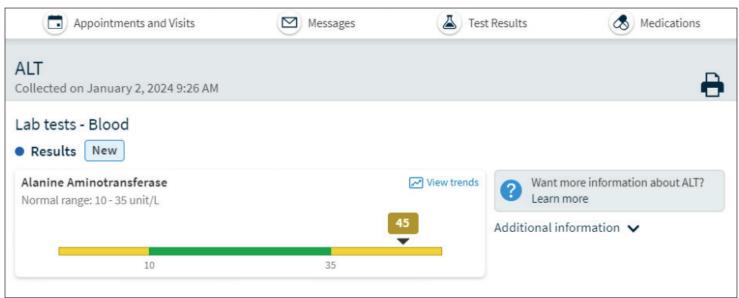




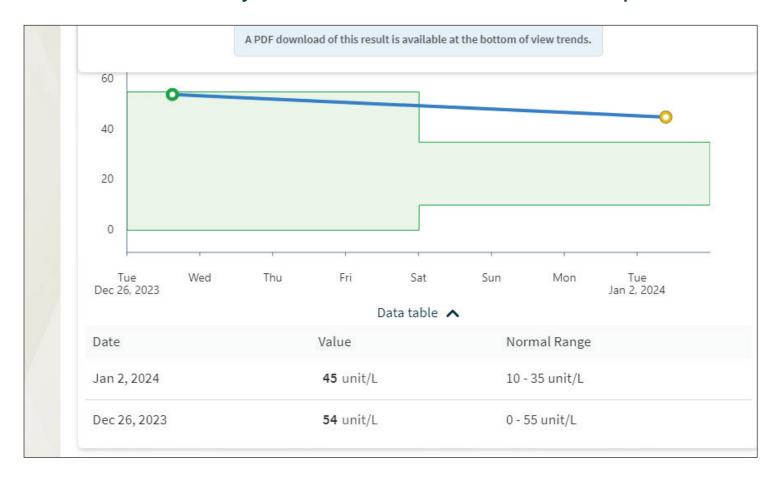


### Reference Range Change Example in MyChart (Patient View)











## **Tumor Marker Updates**

### **Changes to Tumor Marker Testing**

On March 1, 2024, Vanderbilt Medical Laboratories will transition to the Roche cobas immunoassay platform for the following tests:

- Alpha-Fetoprotein (LAB559, AFP)
- Carcinoembryonic Antigen (LAB57, CEA)
- Cancer Antigen 125 (LAB155, CA125)

The new tests are electrochemiluminescence immunoassays "ECLIAs" whereas the old method was Chemiluminescent Microparticle Immunoassay "CMIA."

#### Key changes to anticipate with the new test include:

- Test results using the new assay are not comparable to previous test results.
- Correlation studies performed at VUMC revealed:
  - Alpha Fetoprotein, ~10% positive bias (i.e., results are 10% higher than the prior method)
  - Cancer Antigen 125, ~20% negative bias
  - Carcinoembryonic Antigen, ~10% positive bias
- No concentration-dependent trend was noted for these differences.

#### Ordering providers should consider re-baselining patients by the new AFP, CA125 and CEA tumor marker methods.

Please contact lab Customer Service at 615-875-5227 (5-LABS) or email Dr. Joe Wiencek (<u>joe.wiencek@vumc.org</u>) or Dr. Romney Humphries (<u>romney.humphries@vumc.org</u>) if you have any questions regarding this change.



# Barcode Labeling for Roche Platform

Label Example	Description	Reason
Data  Z Senum Sep Cito.  25 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	Incorrect	Barcode label incorrectly placed, must be parallel to tube edge
TEST TEST	Incorrect	Label is sticking out from tube
	Incorrect	Barcode partially covered with stripes, not readable
	Incorrect	Damaged barcode
SSS EN WINN SA	Incorrect	Not enough window to see the sample on the tube because of barcode placement
EN SE CONTROLLED DE LA	Correct	Correct placement of barcode label