Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2004557	09/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Hematology Oncology, Llc	5000 Park St N Ste 1017 North, Saint Petersburg, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced recertification survey was conducted on 08/25/22 to 09/06/22 at Comprehensive Hematology Oncology LLC. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 12:36 PM on 08/31/22. The laboratory failed to run daily normal and abnormal controls each day of patient testing for flow cytometry. (See Condition D5400 and Standard D5475). The following Conditions were not met: D5400 - Analytic systems 493.1250 D6108 - Laboratory Technical Supervisor 493.1447
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with the General Supervisor and the Laboratory Director, the laboratory failed to maintain temperatures in the acceptable range for storage of chemistry calibration materials and chemistry quality controls (See D5413), failed to document all instrument maintenance for the "COBAS INTEGRA 400 plus analyzer" and "cobas e 411 analyzer" (See D5429), failed to ensure pipettes used for flow cytometry had been checked for adequate and consistent delivery (See D5431), failed to perform color compensation when changing lot numbers of Flow Set Pro Fluorospheres (See D5435), failed to perform chemistry calibration verifications every 6 months for tests performed on the Cobas Integra 400 Plus chemistry analyzer (See D5439), failed to verify the manufacturer's

	recommended ranges for chemistry controls and failed to perform lot to lot verification for flow check and flow set (See D5469), and failed to run a normal and abnormal control each day testing was performed on the Beckman Coulter Navios EX Flow Cytometer to ensure accuracy of test results (See D5475).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the General Supervisor and the Laboratory Director, the laboratory failed to verify Freezer #1 and Freezer #2 maintained temperatures in the acceptable range for storage of chemistry calibration materials and chemistry quality controls for two of two years reviewed (2020-2022). Findings Included: During a tour of the laboratory on 08/25/22 at 10:00 AM Freezer #1 was observed to contain the following expired kits for performance of calibration verification: Validate Tumor Markers Test Set, Validate IBC (iron-binding capacity) Test Set, and Validate Anemia Test Set, which all documented a storage temperature range of -10 to -25 degrees Celsius. On August 25, 2022 at 3:35 PM, the General Supervisor confirmed that the kits were expired, were no longer in use, and needed to be disposed of. The General Supervisor revealed Freezer #1 was frost free, and a temperature log was still being maintained for Freezer #1. The General Supervisor was unable to demonstrate that Freezer #1 maintained temperatures between -10 to -25 degrees Celsius. Review of the policy and procedures signed by the Laboratory Director on 02/01/2021 revealed "Equipment is maintained and calibrated according to manufacturer's recommendations." Record review of Freezer #1's "All about the Use & Care of your Refrigerator" document confirmed the freezer was frost free. On August 26, 2022 at 05:20 PM, the Laboratory Director stated she was unaware that Freezer #1 was frost free, and the laboratory had not verified that Freezer #1 stayed within temperature range even during the defrost cycle. Additional observation on 08 /25/22 at 10:00 AM revealed Freezer #2 contained quality controls. Record review of the COBAS manufacturer's instructions revealed the quality controls must be stored at -15 to -25 degrees Celsius. Review of the "Daily Laboratory Log Sheet" revealed 62 out 562 freezer temperatures for Freezer #2 were out of range: 1. August 2, 2020: "-14.5 degrees Celsius" 2. August 3, 2020: "-14.3 degrees Celsius" 3. August 23, 2020: "-11.6 degrees Celsius" 4. August 25, 2020: "-11.6 degrees Celsius" 5. August 26, 2020: "-13.6 degrees Celsius" 6. January 24, 2021: "-10 degrees Celsius" 7. February 11, 2021: "-11.9 degrees Celsius" 8. February 14, 2021: "-14.4 degrees Celsius" 9. February 15 2021: "-9.7 degrees Celsius" 10. February 16, 2021: "-13.3 degrees Celsius" 11. February 17, 2021: "-11.8 degrees Celsius" 12. February 18, 2021: "-9.8 degrees Celsius" 13. February 21, 2021: "-13.4 degrees Celsius" 14. February 22, 2021: "-10.1 degrees Celsius" 15. February 23, 2021: "-13.3 degrees Celsius" 16. February 24, 2021: "-13.4 degrees Celsius" 17. February 25, 2021: "-13.9 degrees Celsius" 18. March 1, 2021: "-12.7 degrees Celsius" 19. March 2, 2021: "-11.9 degrees Celsius" 20. March 3, 2021: "-12.8 degrees Celsius" 21. March 4,

	2021: "-14.3 degrees Celsius" 22. March 8, 2021: "-14.5 degrees Celsius" 23. March 10, 2021: "-10.4 degrees Celsius" 24. March 11, 2021: "-14.5 degrees Celsius" 25. March 14, 2021: "-13.3 degrees Celsius" 26. March 15, 2021: "-12.2 degrees Celsius" 27. March 18, 2021: "-12.8 degrees Celsius" 28. March 22, 2021: "-14.9 degrees Celsius" 29. March 23, 2021: "-14.3 degrees Celsius" 30. March 26, 2021: "-11.3 degrees Celsius" 31. March 29, 2021: "-11.2 degrees Celsius" 32. April 1, 2021: "-12.6 degrees Celsius" 33. April 4, 2021: "-14.8 degrees Celsius" 34. April 6, 2021: "-13.6 degrees Celsius" 35. April 7, 2021: "-12.5 degrees Celsius" 36. April 11, 2021: "-11.7 degrees Celsius" 37. April 13, 2021: "-13.9 degrees Celsius" 38. April 14, 2021: "-10.2 degrees Celsius" 39. April 18, 2021: "-13.1 degrees Celsius" 40. April 20, 2021: "-11.2 degrees Celsius" 41. April 21, 2021: "-12.2 degrees Celsius" 42. April 22, 2021: "-12.2 degrees Celsius" 43. April 26, 2021: "-11.7 degrees Celsius" 44. April 27, 2021: "-13.8 degrees Celsius" 45. May 2, 2021: "-12.1 degrees Celsius" 46. May 4, 2021: "-12.0 degrees Celsius" 47. May 5, 2021: "-10.1 degrees Celsius" 48. May 9, 2021: "-13.1 degrees Celsius" 49. May 10, 2021: "-10.0 degrees Celsius" 50. May 11, 2021: "-12.6 degrees Celsius" 51. May 12, 2021: "-12.2 degrees Celsius" 52. May 13, 2021: "-7.5 degrees Celsius" 53. May 16, 2021: "-12.1 degrees Celsius" 54. May 17, 2021: "-12.0 degrees Celsius" 55. May 18, 2021: "-11.0 degrees Celsius" 56. May 19, 2021: "-11.8 degrees Celsius" 57. May 20, 2021: "-13.0 degrees Celsius" 58. May 23, 2021: "-11.5 degrees Celsius" 59. May 25, 2021: "-11.4 degrees Celsius" 60. May 26, 2021: "-12.0 degrees Celsius" 61. May 27, 2021: "-12.2 degrees Celsius" 62. May 31, 2021: "-12.1 degrees Celsius" On 08/25/2022 at 3:55 PM, the General Supervisor stated she did not know what the exact acceptable range was supposed to be for Freezer #2. On 08/25/22 at 5:20 PM, the Laboratory Director was unaware that Freezer #2's temperature log had unacceptable temperature ranges for the items stored.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor and Laboratory Director, the laboratory failed to document all instrument maintenance for the "COBAS INTEGRA 400 plus analyzer" and "cobas e 411 analyzer" for 2 of 2 years reviewed (2020-2022). Findings included: Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" logs revealed that not all weekly maintenance (System Power Off/Power On, Clean ISE tower automatically, backup database, clean probes and splash guard), monthly maintenance (Clean Waste box fitting, Clean ISE tower manually), quarterly maintenance (Replace ventilation filters, Replace external water reservoir, Clean /lubricate rotor, Clean external water and Clean fluid waste reservoir) and semi-annual maintenance (Clean internal water reservoir, Clean wash station, Clean instrument, and Replace ISE tubing) was documented. Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "System Power Off/Power On" was not documented on the following weeks of testing: 6/15/20-6/19/20, 8/3/20-8/07/20, 9/7/20-9/11/20, 9/21/20-9/25/20, 11/2/20- 11 /6/20, 11/9/20-11/13/20, 11/16/20- 11/20/20, 08/23/21-08/27/21, 09/20/21-09/24/21, 09/27/21-10/01/21, 11/15/21-11/19/21, 12/06/21-12/10/21, 12/13/21-12/17/21, 12/20

/21-12/24/21, 01/10/22-01/14/22, 01/24/22-01/28/22, 01/31/22- 02/04/22, 02/21/22-02/25/22, 06/13/22-06/17/22, 06/20/22-06/24/22, and all weeks of testing for December 2020, March 2021, April 2021, June 2021, July 2021, October 2021, and April 2022. Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean ISE tower automatically" was not documented on the following weeks of testing: 08/03/20-08/07/20, 08/10/20-08/14/20, 08/24/20-08/28/20, 09/06/21-09/10/21, 09/20/21-09/24/21, 09/27/21-10/01/21, 10/04/21-10/08/21, 10/18/21-10/22/21, 10/25/21-10/29/21, 12/06/21-12/10/21, 01/03/22-01/07/22, 01/10/22-01/14/22, 02/21/22-02/25/22, 04/11/22-04/15/22, 04/18/22-04/22/22, 04/25/22-04/29/22, 05/09/22-05/13/22, 05/23/22-05/27/22, 06/13/22-06/17/22, 06/20/22-06/24/22, 08/15/22-08/19/22, and all weeks of testing for September 2020, October 2020, November 2020, December 2020, January 2021, March 2021, April 2021, June 2021, July 2021, August 2021, November 2021, March 2022 and July 2022. Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Backup Database" was not documented on the following weeks of testing: 08/17/20-08/21/20, 08/24/20-08/28/20, 08/31/20-09/04/20, 09/07/20-09/11/20, 09/14/20- 09/18/20, 11/02/20-11/06/20, 11/09/20-11/13/20, 11/16/20-11/20/20, 11/30/20-12/04/20, 08/09/21-08/13/21, 08/23/21-08/27/21, 08/30/21-09/03/21, 10/04/21-10/08/21, 10/11/21-10/15/21, 10/25/21-10/29/21, 12/06/21-12/10/21, 01/03/22-01/07/22, 03/07/22-03/11/22, 03/14/22-03/18/22, 03/21/22-03/25/22, 04/11/22-04/15/22, 04/18/22-04/22/22, 04/25/22-04/29/22, 06/13/22-06/17/22, 06/20/22-06/24/22, 07/11/22-07/15/22, 07/18/22-07/22/22, and all weeks of testing for October 2020, March 2021, April 2021, June 2021, July 2021, and November 2021. Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean probes and splash guard" was not documented on the following weeks of testing: 07/20/20-07/24/20, 07/27/20-07/31/20, 08/31/20-09/04/20, 09/07/20-09/11/20, 09/21/20-09/25/20, 09/28/20-10/02/20, 11/30/20-12/04/20, 04/12/21-04/16/21, 04/19/21-04/23/21, 07/05/21-0709/21, 07/12/21-07/16/21, 07/25/21-07/30/21, 08/30/21-09/03/21, 10/04/21-10/08/21, 10/25/21-10/29/21, 12/06/21-12/10/21, 02/07/22-02/11/22, 03/07/22-03/11/22, 03/21/22-03/28/22, 04/11/22-04/15/22, 04/18/22-04/22/22, 04/25/22-04/29/22, 05/02/22-05/06/22, 06/13/22-06/17/22, 06/20/22-06/29/22, 07/04/22-07/08/22, 08/15/22- 8/19/22, and all weeks of testing for December 2020 and November 2021. Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean waste box fitting" was not documented for the following months of testing: July 2020, August 2020, October 2020, November 2020, December 2020, March 2021, May 2021, December 2021, and March 2022. Record review of the "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean ISE tower manually" was not documented for the following months of testing: October 2020, November 2020, December 2020, May 2021, November 2021, December 2021, March 2022, May 2022, and July 2022. Record review of the quarterly "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Replace ventilation filters" was not documented for 4 out of 8 quarters of testing: 4th quarter 2020, 3rd quarter 2021, and 1st and 2nd quarter of 2022. Record review of the quarterly "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Replace external water reservoir filter" was not documented for 8 out of 8 quarters of testing: 3rd and 4th quarters 2020, 1st - 4th quarters 2021, and 1st and 2nd quarter 2022. Record review of the quarterly "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean/Lubricate rotor" was not documented for 7 out of 8 quarters of testing: 3rd and 4th quarters 2020, 1st-4th quarters 2021, and 2nd quarter 2022. Record review of the quarterly "COBAS INTEGRA 400 plus analyzer Daily

Checklist, Maintenance Log, & General Procedures" revealed "Clean external water reservoir" was not documented for 7 out of 8 quarters of testing: 3rd and 4th quarters 2020, 1st, 3rd and 4th quarters 2021, and 1st and 2nd quarter 2022. Record review of the quarterly "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean fluid waste reservoir" was not documented for 8 out of 8 quarters of testing: 3rd and 4th quarters 2020, 1st - 4th quarters 2021, and 1st and 2nd quarter 2022. Record review of the semi-annual "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean internal water reservoir" was not documented for 3 out of 4 events of testing: 2nd event 2020, 1st event 2021, and 1st event 2022. Record review of the semi-annual "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean wash station" was not documented for 2 out of 4 events of testing: 2nd event 2020 and 1st event 2022. Record review of the semi-annual "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Clean Instrument" was not documented for 1 out of 4 events of testing: 2nd event 2020. Record review of the semi-annual "COBAS INTEGRA 400 plus analyzer Daily Checklist, Maintenance Log, & General Procedures" revealed "Replace ISE tubing" was not documented for 2 out of 4 events of testing: 2nd event 2020 and 1st event 2021 Record review of the "cobas e 411 analyzer Maintenance Log" revealed that not all weekly maintenance (Clean incubator and aspiration station and Clean sipper probe), every two weeks maintenance (Clean rinse station and Perform liquid flow cleaning), and monthly maintenance (Replace pinch valve tubing) was documented. Record review of the "cobas e 411 analyzer Maintenance Log" revealed "Clean incubator and aspiration station" was not documented for the following weeks of testing: 09/21/20-09/25/20, 07/5/21-07/09/21, 07/19/21-07/23/21, 07/26/21-07/30/21, 11/01/21-11/05/21, 11/15/21-11/19/21, 11/22/21-11/26/21, 11/29/21-12/03/21, 12/06/21-12/10/21, 12/13/21-12/17/21, 01/24/22-01/28/22, 03/07/22-03/11/22, 03/14/22-03/18/22, 03/28/22-04/01/22, 04/11/22-04/15/22, 04/18/22-04/22/22, 05/01/22-05/06/22, 05/09/22-05/13/22, 05/16/22-05/20/22, 05/30/22-06/03/22, 06/27/22-07/01/22, 07/18/22-07/22/22, 08/01/22-08/05/22, and 08/15/22-08/19/22, and all weeks of testing in July 2020, August 2020, October 2020, November 2020, December 2020, January 2021, February 2021, March 2021, April 2021, May 2021, October 2021, and February 2022. Record review of the "cobas e 411 analyzer Maintenance Log" revealed "Clean sipper probe" was not documented for the following weeks of testing: 09/21/20-09/25/20, 07/12/21-07/16/21, 07/19/21-07/23/21, 07/26/21-07/30/21, 12/06/21-12/10/21, 12/13/21-12/17/21, 05/01/22-05/06/22, 05/09/22-05/13/22, 05/16/22-05/20/22, 05/30/22-06/03/22, 06/27/22-07/01/22, 07/18/22-07/22/22, 08/01/22-08/05/22, and 08/15/22-08/19/22, and all weeks of testing in July 2020, August 2020, October 2020, November 2020, December 2020, January 2021, February 2021, March 2021, April 2021, May 2021, November 2021, January 2022, February 2022, March 2022, and April 2022. Record review of the "cobas e 411 analyzer Maintenance Log" revealed "Clean rinse station" was not documented every two weeks of testing for the following: 6/14/21-6/30/21 and the entire months of June 2020 through May 2021 and July 2021 through July 2022. Record review of the "cobas e 411 analyzer Maintenance Log" revealed "Performed liquid flow cleaning" had not been documented every two weeks of testing for the following: 11/16/20-11/27/20, 07/19/2021- 07/30/21, 10/04/21-10/15/21, 01/31/22-02/11/22, 02/28/22-03/11/22, 05/02/22-05/13/22, 07/04/22-07/15/22 and the entire months of July 2020 through October 2020, January 2021, April 2021, and May 2021. Record review of the "cobas e 411 analyzer Maintenance Log" revealed "Replace pinch valve tubing" had not been documented monthly for the following: July 2020 through February 2021, April 2021 through August 2021, and October 2021 through July 2022. Record review of the laboratory's policy "Instrument

	Maintenance" revealed "Fulfill all maintenance as outlined in the manufacturer's System Operating manuals. Be sure all maintenance is documented in a neat orderly manner." On 08/25/22 at 4:00 PM, the General Supervisor stated she sometimes forgets to document maintenance. On 08/26/22 at 05:15 PM, the Laboratory Director revealed she was unaware the General Supervisor was not documenting all maintenance for the chemistry analyzers.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with the General Supervisor and Laboratory Director, the laboratory failed to ensure 2 Microlit pipettes (2-20 and 20-200 microliter) used for flow cytometry had been checked for adequate and consistent delivery for two out of two years reviewed (2020 - 2022) Findings included: Observation on 8/26/22 at 9:30 AM revealed 2 Microlit pipettes (2-20 and 20-200 microliter) by the flow cytometry instrument. Review of the Microlit "Micropipette Product Manual" revealed performance checks should be conducted every 3-6 months depending on use and the samples aspirated to check the accuracy and precision of the pipette. Review of pipette calibrations records revealed no evidence of pipette calibration records since the last recertification survey ending on 5/19/2020. Record review of the laboratory's procedure "Instrument Maintenance" revealed "Instrument Maintenance involves keeping laboratory equipment in good working order." On 08 /26/22 at 9:45 AM, the General Supervisor stated the pipettes had been calibrated, but she could not find the calibration reports. On 08/26/22 at 5:25 PM, the Laboratory Director reported she was unaware the pipettes in the laboratory had not been calibrated for the last 2 years.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor, the laboratory failed to perform color compensation when they changed lot numbers of Flow Set Pro Fluorospheres on the Beckman Coulter Navios EX Flow Cytometer on 10/19/2021. Findings included: Review of the package insert for the Flow Set Pro Fluorospheres states "Run the new and old lots in parallel, according to the laboratory's established

	procedures, to determine the average target channels and HV [High Voltage] and/or Gain Range for the new lot number." Review of the Flow Cytometry procedure titled Cytometry Quality Control stated "Changes in PMT [Photomultipler Tube] voltages effectively change the sensitivity of the detector; therefore whenever the voltage is changed for a fluorescence channel, it is necessary to reset the compensation matrix." Review of the flow set Levey-Jennings Charts showed a new lot number of flow set was put in use on 10/19/2021. Review of quality control documents revealed there was not color compensation performed on 10/19/2021. On 08/25/2022 at 4:23 PM, the General Supervisor stated she had not performed color compensation.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on chemistry calibration verification (linearity) record review, policy review, and interview with the General Supervisor and Laboratory Director, the laboratory failed to perform chemistry calibration verifications every 6 months for uric acid, carbon dioxide, iron, albumin, blood urea nitrogen, calcium, chloride, glucose, potassium, magnesium, sodium, phosphorus, total protein, and creatinine tests that were performed on the Cobas Integra 400 Plus chemistry analyzer for 2 of 2 years reviewed (2020-2022). Findings included: Review of calibration verification records for the Cobas Integra 400 Plus Chemistry analyzer revealed calibration verifications for uric acid, carbon dioxide, iron, albumin, blood urea nitrogen, calcium, chloride, glucose, potassium, magnesium, sodium, and phosphorus tests had been performed 07 /26/20, 07/15/21, and 08/19/22. The calibration verification for total protein had been performed 06/11/20 and 05/13/22, and the calibration verification for creatinine had been performed 07/07/21. Record review of the laboratory's policy titled "Linearity /Calibration Verification" revealed "2. Criteria Frequency: Performed as frequent as manufacturer specifies, but no less than [sic] least once every 6 months." Record review of the laboratory's "Monthly Quality Assurance Assessment" for March 2021, April 2021, and May 2021 revealed a Quality Control Policy documenting linearity verification would be performed and documented on the Cobas Integra 410 [sic] and

	411 [sic] every six months. In the column next to this policy was an area to document yes, no, not applicable, or comments. This column documented "...next due March 2021, Overdue." Review of the June 2021 "Monthly Quality Assurance Assessment" revealed the comment linearity verification was over-due, being processed. Some kits are back ordered. Review of the "Monthly Quality Assurance Assessment" for August 2021 through December 2021 revealed all linearity verifications were completed in July of 2021 and were due next November 2021. Review of the January 2022 "Monthly Quality Assurance Assessment" revealed linearity verifications were completed in December of 2021 and were next due in June of 2022. On 08/25/22 at 2: 25 PM, the General Supervisor stated she knew linearities needed to be performed every 6 months but sometimes, she didn't have the time to perform the linearities. On 08/26/22 at 5:05 PM, the Laboratory Director stated she was unaware that the General Supervisor had not performed all of the required linearities.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor and Laboratory Director, the laboratory failed to verify the manufacturer's recommended ranges for the "Precipath U Plus" and "Precinorm U plus" quality controls for alanine transaminase, alkaline phosphatase, aspartate aminotransferase, total and direct bilirubin, blood urea nitrogen, calcium, carbon dioxide, chloride, creatinine, glucose, iron, lactate dehydrogenase, magnesium, phosphorous, potassium, sodium, total protein, uric acid, and urine iron binding capacity, and "PreciControl Varia" quality controls for Vitamin B12, ferritin and folate for two out of two years reviewed (2020 - 2022). The laboratory failed to verify the acceptability for the unassayed Flow Check Pro Fluorospheres and Flow Set Pro Fluorospheres through concurrent testing of control materials before using the new lot number of controls for flow check and flow set on 10/19/2021. Findings included: Review of Chemistry quality control records revealed the lack of quality controls records for verification of recommended ranges for the new lots of Precipath U Plus" and "Precinorm U plus" quality controls and "PreciControl Varia" quality controls. Review of the laboratory's policy "Quality Assurance" revealed "New lot numbers of reagents, test kits, and media are verified for quality using QC material before use." Review of the laboratory's "Monthly Quality Assurance Assessment" revealed that monthly assessments from January 2021 to July 2022 included "Parallel testing performed on new lot numbers of controls for Roche 410 [sic] and 411" and documented "Yes" to being done. Review of the Levey-Jennings charts for flow check showed the laboratory was using flow check lot

	number 9311679 from 02/02/2021 to 10/15/2021, and started using lot number 9311744 on 10/19/2021 to 02/19/2022. Review of the Levey-Jennings charts for flow set showed the laboratory was using flow set lot number 9001098 from 02/02/2021 to 10/15/2021, and started using lot number 9001106 on 10/19/2021 to 02/19/2022. Review of the package inserts for the Flow-Set Pro Fluorospheres provided the following instructions, "Use this procedure when changing lots of Flow-Set Pro Fluorospheres. Run the new and old lots in parallel, according to the laboratory's established procedures, to determine the average target and HV and/or Gain ranges for the new lot." Review of the Flow Cytometry procedure manual that was signed and dated by the Laboratory Director on 02/01/2021, revealed it did not contain a procedure for performing a lot to lot comparison of the current lot number to the new lot number of flow set. On 08/25/22 at 11:00 AM, the General Supervisor stated she only verified the new lot of hematology controls. On 08/26/22 at 5:10 PM, the Laboratory Director stated she was unaware that the General Supervisor was not verifying new lots of chemistry controls and new lots of flow check and flow set for flow cytometry. On 08/26/22 at 5:57 PM, the General Supervisor stated there was no lot to lot comparison of the flow check and flow set.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, and interview with the General Supervisor and the Laboratory Director, the laboratory failed to run a normal and abnormal control each day testing was performed on the Beckman Coulter Navios EX Flow Cytometer from 02/02/2021 to 01/19/2022. Findings included: The laboratory did perform a "10-Color Monthly Antibody Positive QC [Quality Control]" on 07/16/2021, 10/12/2021, 11/19 /2021 and 12/03/21. Review of the "QC: 10-Color Monthly Antibody Positive QC" showed a positive control was reviewed by the Technical Supervisor for Flow Cytometry on 07/29/2021, 10/26/2021, 11/29/2021, and 12/30/2022. Review of the Flow Cytometry procedure manual that was signed and dated by the Laboratory Director on 02/01/2021, did not contain a procedure for an Individualized Quality Control Plan (IQCP). Review of the laboratory's policy and procedure titled "Cytometer Quality Control" revealed no written procedures to run a daily normal and abnormal control on each day of testing in accordance with CLIA requirements. Review of the patient logs showed the first day of patient testing was on 02/02/2021 and the last day of testing was 1/19/2022. The patient logs showed a total of 494 patient's specimens (396 peripheral blood specimens and 98 bone marrow specimens) were tested by the laboratory on the flow cytometer, and the results were reported by another laboratory. The laboratory used the flow cytometer to diagnose and monitor leukemia and lymphoma. The laboratory evaluated the following antibodies: CD2 (Cluster of Differentiation 2, T cell lymphocytic marker), CD3 (T cell lymphocytic marker), CD4 (T cell lymphocytic marker), CD5 (T cell lymphocytic marker), CD7 (T cell lymphocytic marker), CD8 (T cells marker), CD10 (follicle center cells marker), CD11c (dendritic cell marker), CD13 (myeloid cells marker), CD14 (monocytes and macrophages marker), CD16 (granulocytes and natural killer cell marker), CD19 (B cell marker), CD20 (B cell marker), CD23 (B cell lymphocytic marker), CD33

	(monocytes and macrophages marker), CD34 (hematopoetic stem cells marker), CD38 (plasma cells and activated T and B cells marker), CD45 (leukocyte marker), CD56 (natural killer cells marker), CD64 (monocytes and macrophages marker), CD117 (stem cell and plasma cells marker), HLA-DR (Human Leukocyte Antigen - DR isotype T cell marker), Kappa (light chain B cell markers), and Lambda (light chain B cell markers). On 08/25/2022 at approximately 10:00 AM, the General Supervisor stated they had stopped testing (1/19/22) due to a billing issue and they were going to resume testing once they received an order for new reagents. On 08/25 /2022 at 4:09 PM, the General Supervisor stated that they did not run a positive and negative control on each day of testing. On 08/25/2022 at 5:04 PM, the Laboratory Director stated they do not have an IQCP. On 08/25/2022 at 5:06 PM, the Laboratory Director stated they do not do a positive and negative control on a daily basis.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the Testing Personnel and the Laboratory Director, the Technical Supervisor for Flow Cytometry failed to provide technical supervision by not establishing an adequate quality control plan in Flow Cytometry in accordance with CLIA (Clinical Laboratory Improvement Amendments) from 02/02 /2021 to 01/19/2022. (see D6117)
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with the Testing Personnel and the Laboratory Director, the Technical Supervisor for Flow Cytometry failed to establish a quality control plan in accordance with CLIA (Clinical Laboratory Improvement Amendments) from 02/02/2021 to 01/19/2022. Findings included: Review of the laboratory's "Job Description High Complexity Duties and Responsibilities Technical Supervisor" revealed the Technical Supervisor was responsible for "Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results." The laboratory failed to run a normal and abnormal control each day testing was performed on the Beckman Coulter Navios EX Flow Cytometer from 02/02/2021 to 01/19/2022. (see D5475)