| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D2077350 | 07/10/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sunnyview Hospital And Rehabilitation Center | 1270 Belmont Avenue, Schenectady, NY | |

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 |
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| **D0000** | A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA validation survey at SUNNYVIEW HOSPITAL AND REHABILITATION CENTER on July 10, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory was found to not be in compliance with all condition-level CLIA requirements. The following condition and standard level deficiencies were found during CLIA exempt-state validation survey performed on July 10, 2024. |
| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the American Proficiency Institute (API) Proficiency Test (PT) records and an interview with the laboratory supervisor, the laboratory failed to rotate proficiency testing for the i-STAT between 54 out of 55 testing personal from 2022 to 2024. Findings Include: 1. On the day of survey, July 10, 2024 at 2:45 pm, review of the API PT records for testing performed on the Abbott i-STAT revealed, 1 out of 55 nurses performed all testing events from 2022 to 2024. 2. The laboratory could not provide documentation for PT being rotated among the other 54 out of 55 testing personnel performing tests on the Abbott i-STAT. 3. The laboratory supervisor confirmed the findings above on July 10, 2024 at 3:00 pm. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish |

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| | and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of competency assessment records, the competency assessment procedure and interview with the laboratory supervisor, the laboratory failed to establish a competency assessment procedure to assess technical supervisors (TS) for their supervisory roles performed from July 2022 to July 2024. Findings Include: 1. On the day of survey, July 10, 2024, review of the competency assessment procedure revealed, the procedure did not include the assessment for TS and their supervisory roles performed in the laboratory from July 2022 to July 2024. 2. On Form CMS 209, there are two TS listed who have not undergone competency assessments for their supervisory roles in the laboratory. 3. The laboratory supervisor confirmed the findings above on July 10, 2024 at 9:30 am. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory records and interview with the laboratory supervisor, the laboratory failed to meet analytic systems requirements in 493.1251 through 493.1283 for the laboratory and point of care testing performed from July 2022 to July 2024. Refer to: D5401, D5403, D5429, and D5447. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures and interview with the laboratory supervisor, the laboratory failed to establish a policy / procedure for the Sysmex XN-550 complete blood count (CBC) analyzer from July 2022 to July 2024. 1. On the day of survey, July 10, 2024 at 2:15 pm, review of the laboratory procedures revealed, the laboratory procedures binder did not include a procedure for the Sysmex XN-550 CBC analyzer. 2. Per Form CMS 116, an estimated 67,594 hematology tests are performed annually. 3. The laboratory supervisor confirmed the finding above on July 10, 2024 at 2:30, as the procedure could neither be found in the binder onsite or in the laboratory's computer system. |
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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the manual differential procedure and interview with the laboratory supervisor, the laboratory failed to include quality control (QC) procedures in the manual differential procedure manual from July 2022 to July 2024. Findings Include: 1. On the day of survey, July 10, 2024, review of the manual differential procedure revealed, the procedure manual did not include steps for performing QC for the manual differential each day of patient testing performed from July 2022 to July 2024. 2. Per Form CMS 116, an estimated 67,594 hematology tests are performed annually. 3. The laboratory supervisor confirmed the finding above on July 10, 2024 at 12:15 pm. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory maintenance records, observation of laboratory instruments operator's manual, and interview with the laboratory supervisor, the laboratory fail to perform and document maintenance for one of one Siemens Clinitek Advantus from July 2022 to July 2024 and have preventative maintenance (PM) performed for one of one Instrumentation Laboratory / Werfen ACL TOP 50 analyzer in May 2024. Findings Include: 1. The Siemens Clinitek Advantus operators guide, 5 Maintenance, states, Performing the Daily Cleaning, "Clean the following parts at least once each day or after 300 strips, which ever is more frequent: Push bar, fixed platform, moving table, urine trip hold down plate". "clean the display screen once a day..." 2. On the day of survey, July 10, 2024, the laboratory was unable to provide documentation of daily cleaning performed on one of one Siemens Clinitek Advantus |

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| | from July 2022 to July 2024. 3. While on tour of the laboratory, a PM sticker was found on one of one Instrumentation Laboratory / Werfen ACL TOP 50 analyzer, that stated 5/24, which the laboratory supervisory found out that is when the PM was due. 4. The laboratory could not provide documents showing that PM had been perform May of 2024. 5. Per Form CMS 116, an estimated 67,594 hematology and 1,944 urinalysis tests are performed annually. 6. The laboratory supervisor confirmed the above finding on July 10, 2024 at 3:00 pm. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality control records and interview with the laboratory supervisor, the laboratory fail to perform QC for 2 of 2 Abbott i-STAT that are used with the CG4+, CHEM 8+, cTnl cartridges at least once each day patient specimens are assayed from July 2022 to July 2024. Finding Include: 1. The point of care testing (POCT) procedures for the Abbott i-STAT CG4+, CHEM 8, and cTnl cartridges, B. Liquid control, "three levels of controls will be performed monthly on each i-STAT meter in each clinical area". 2. On the day of survey, July 10, 2024, at 10:45 am, the laboratory provided incomplete individual quality control plans (IQCP), as each IQCP for the Abbott i-STAT CG4+, CHEM 8, and cTnl cartridges only included the risk assessment. 3. Per Form CMS 116, an estimated 67,594 hematology and 11,923 chemistry tests are performed annually. 4. The laboratory supervisor confirmed the findings above July 10, 2024, at 11:00 am. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory quality assessment (QA) programs and interview with the laboratory supervisor, the laboratory director failed to ensure QA programs in place, reviewed the pre-analytical, analytical and post - analytical processes of the point of care testing (POCT) laboratory from July 2022 to July 2024. 1. On the day of survey, July 10, 2024 at 10:35 am, review of the QA quarterly audits revealed, the laboratory audits analyzed different areas of the laboratory each quarter. 2. The laboratory could not provide documentation for quality audits performed for the POCT laboratory. 3. The laboratory supervisory confirmed on July 10, 2024 at 3:00 pm that the QA program did not include the review of the POCT. |
| **D6108** | LABORATORY TECHNICAL SUPERVISOR<br>CFR(s): 493.1447 |

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| | 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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory personnel educational credential records and interview with the laboratory supervisor, the technical supervisor (TS) failed to qualify to perform their supervisory TS responsibilities in the laboratory from July 2022 to July 2024. Refer to D6109. |
| **D6109** | TECHNICAL SUPERVISOR QUALIFICATIONS<br>CFR(s): 493.1449<br><br>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory personnel educational credential records and interview with the laboratory supervisor, the technical supervisor (TS) failed to qualify to perform their supervisory TS responsibilities in the laboratory from July 2022 to July 2024. Findings Include: 1. On July, 8, 2024, the laboratory supervisor provided an Associates Degree in Nursing, but was unable to provide documentation of an earned bachelors degree. 2. The laboratory supervisor performs and signs off on testing personnel competency assessment records and signs off on monthly record reviews. 3. The laboratory supervisor confirmed the findings above on July 8, 2014 at 3:00 pm. |
| **D6125** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of competency assessment records and interview with the laboratory supervisor, the laboratory failed to assess 54 out of 55 nurses for the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples from 2022 to 2024. Findings Include: 1. On the day of survey, July 10, 2024 at 2:45 pm, review of the American Proficiency Institute (API) proficiency testing records for testing performed on the Abbott i-STAT revealed, 1 out of 55 nurse performed all testing events from 2022 to 2024. 2. Review of all 55 nurses competency assessment records from 2023 revealed, their annual competency assessment did not include the assessment of test performance through |

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| | testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 3. The laboratory supervisor confirmed the findings above on July 10, 2024 at 3:00 pm. |
| **D8103** | BASIC INSPECTION REQUIREMENTS<br>CFR(s): 493.1773(b)(c)(d)<br><br>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on the lack of documentation and interview with the laboratory supervisor, the laboratory failed to provide testing personnel records within a reasonable time frame during the course of the inspection performed on July 10, 2024. Findings Include: 1. On the day of survey, July 10, 2024 the laboratory was requested to provide educational documents for the follow personnel: - 55 nurses performing testing with the Abbott i-STAT. 2. The above document were not received by the end of survey (July 10, 2024 at 3:30 pm), as the documents are kept at a different laboratory campus. |
| **D8401** | INSPECTION OF CLIA-EXEMPT AND ACCREDITED LABS<br>CFR(s): 493.1780<br><br>(a) Validation inspection. CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation. (b) Complaint inspection. CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part. (c) Noncompliance determination. If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur: (c)(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and 488.11 of this chapter. (c)(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program. (d) Compliance with basic inspection requirements. CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in 493.1773. |

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| | This STANDARD is not met as evidenced by:<br>Based on the CLIA-exempt laboratory validation survey, the laboratory failed to comply with the basic inspection requirements in 493.1773. Refer to 8301 |