

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2227218	(X3) Date Survey Completed 04/05/2023
Name of Provider or Supplier Solvera Healthcare Center Inc	Street Address, City, State 3525 N University St, Peoria, IL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel one (TP1); the laboratory failed to enroll in proficiency testing challenges from March 15, 2022, till the date of the survey, April 5, 2023 for six of six Hematology analytes: Hematocrit, Hemoglobin, Platelet, Red Blood Cell Count, White Blood Cell Count, and automated White Blood Cell Differentials. Findings Include: 1. No documentation was found to confirm the laboratory had enrolled in proficiency testing for six of six regulated analytes: Hematocrit, Hemoglobin, Platelet, Red Blood Cell Count, White Blood Cell Count, and automated White Blood Cell Differentials. 2. During the survey on 04-05-2023, at 11:06 am, TP1 confirmed the facility had not enrolled in proficiency testing challenges for six of six regulated hematology analytes reported by the laboratory.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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</p>

examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, lack of documentation, and interview with Testing Personnel one (TP1); the laboratory failed to have written procedures for Complete Blood Count (CBC) testing performed in the specialty of hematology. Findings Include: 1. Review of the laboratory's procedure manual found no written procedures for CBC testing performed on the Abbott CELL-DYN Emerald analyzer. 2. On survey date 04-05-2023, at 10:24 am, TP1 confirmed no individual written procedure were available for CBC testing.

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 review of laboratory records, lack of documentation, and interview with Testing Personnel three (TP3); the laboratory failed to monitor the laboratory's room temperature and humidity for hematology testing performed on March 15, 2022, through the date of survey on April 5, 2023. Findings Include: 1. Review of Performance Characteristics and Specifications in section four of the CELL-DYN Emerald 22 Operator's Manual stated, "Operating Temperature from 64-9. degrees Fahrenheit and Relative Humidity of 80% maximum at 89.6 degrees Fahrenheit. 2. No documented room temperature and humidity records were found during the survey. 3. On survey date 04-05-2023, at 11:44 am TP3 confirmed the laboratory did not document maintenance or monitor the room temperature or humidity of the laboratory.

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 review of laboratory records, lack of documentation and interview with Testing Personnel three (TP3); the laboratory failed to perform and document maintenance as defined by the manufacturer for hematology testing performed on the CELL-DYN Emerald analyzer from March 15, 2022, through April 5, 2023. Findings include: 1. Review of the manufacturer's operator's manual for the CELL-DYN Emerald analyzer section 9 defines the maintenance procedures and stated "The CELL-DYN Emerald 22 System has been designed to require minimal routine

maintenance. To ensure optimum performance, the operator is encouraged to routinely perform the scheduled maintenance procedures described in this section. Failure to perform recommended maintenance can result in inaccurate or imprecise results." 2. Review of the manufacturer's operator's manual for the CELL-DYN Emerald analyzer section 9, Preventive Maintenance Schedule stated, a. "Weekly Maintenance, Bleach Cleaning the system with a bleach solution is performed weekly or as needed when a parameter is repeatedly rejected." b. "Quarterly Maintenance, Lubricating the Pistons for optimal operation, the Syringe Pistons should be lubricated every three months." c. "As Needed Maintenance." 3. No records were found to document the weekly, quarterly, and as needed maintenance for the CELL-DYN Emerald analyzer. 4. Interview with TP3 on 04-05-2023 at 11:44 am confirmed the laboratory failed to document/perform all maintenance activities as required by the manufacturer for the CELL-DYN Emerald analyzer.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview with Testing Personnel two (TP2); the laboratory failed to identify the Testing Personnel who performed the Complete Blood Count (CBC) testing for nine of nine patient testing records reviewed for the specialty of hematology. Findings Include: 1. Review of laboratory testing records found the laboratory failed to maintain records to identify the testing personnel that had performed the CBC testing for the following patient test records: Testing Date Medical Record Number 04-01-2022 13247 07-01-2022 14353 08-18-2022 16345 09-28-2022 9583 11-25-2022 18833 01-16-2023 55381 03-15-2023 56333 03-23-2023 56159 03-29-2023 55517 2. On survey date 04-05-2023, at 2: 35 pm, TP3 confirmed that the laboratory does not record or document the Testing Personnel that performs the CBC testing.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with Testing Personnel one (TP1); the

	<p>laboratory failed to have a system to ensure results are accurately transferred from the Abbott CELL-DYN Emerald analyzer to the Electronic Medical Record (EMR). Findings Include: 1. No documentation was found to show the laboratory had a system in place to ensure results are accurately transferred from the Abbott CELL-DYN Emerald analyzer to the EMR. 2. On survey date 04-05-2023, at 2:45 pm, TP1 confirmed the laboratory failed to ensure results are accurately transferred from the Abbott CELL-DYN Emerald analyzer to the EMR.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on lack of documentation and interviews with Testing Personnel one (TP1) and Testing Personnel two (TP2); the laboratory director failed to ensure the overall management and direction for the specialty of hematology. Findings Include: 1. The laboratory director failed to ensure the laboratory enrolled in proficiency testing challenges for six of six Hematology analytes: Hematocrit, Hemoglobin, Platelet, Red Blood Cell Count, White Blood Cell Count, and automated White Blood Cell Differentials. See D6015. 2. The laboratory director failed to ensure quality control and quality assessment programs were established and maintained to identify failures in quality as they occur. See D6022. 3. The laboratory director failed to ensure an approved written procedures for Complete Blood Count (CBC) testing performed were available to all personnel. See D6031.</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel one (TP1); the laboratory director failed to ensure the laboratory was enrolled in proficiency testing challenges from March 15, 2022, till the date of the survey, April 5, 2023, for six of six Hematology analytes: Hematocrit, Hemoglobin, Platelet, Red Blood Cell Count, White Blood Cell Count, and automated White Blood Cell Differentials. Findings Include: 1. The laboratory failed to enroll in proficiency testing challenges from March 15, 2022, till the date of the survey, April 5, 2023, for six of six Hematology analytes: Hematocrit, Hemoglobin, Platelet, Red Blood Cell Count, White Blood Cell Count, and automated White Blood Cell Differentials. See D2000.</p>
<p>D6022</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of laboratory documentation, and interviews with Testing Personnel one (TP1) and Testing Personnel two (TP2); the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to identify failures in quality as they occur. Findings Include: 1. Review of laboratory records found no documented Quality Control (QC) and Quality Assurance (QA) policies. 2. Review of laboratory records found no documented QA monitoring for Complete Blood Count performed from March 15, 2022, to date of survey April 5, 2023. 3. Review of laboratory documents and lack of laboratory documentation showed the laboratory failed to have policies and procedures in place to monitor, assess, and when indicated correct problems when identified. 4. On survey date 04-05-2023, at 11:08 am, TP1 confirmed the laboratory failed to have written policies for QC ad QA. 5. On survey date 04-05-2023, at 2:35 pm, TP2 confirmed the laboratory failed to document corrective actions on a log or worksheet for hematology testing.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, lack of documentation, and interview with Testing Personnel one (TP1); the laboratory director failed to ensure that approved written procedures for Complete Blood Count (CBC) testing were available to all personnel. Findings Include: 1. The laboratory failed to have written procedures for Complete Blood Count (CBC) testing performed in the specialty of hematology. See D5401.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

	<p>Based on lack of documentation and interview with Testing Personnel one (TP1); the technical consultant failed to ensure oversight for the specialty of hematology. Findings Include: 1. The technical consultant failed to evaluate the competency of four out of four testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. See D6046.</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with Testing Personnel one (TP1); the technical consultant failed to evaluate the competency for hematology testing on the CELL-DYN Emerald for four out of four testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings Include: 1. Review of the laboratory's Competency Assessment of Laboratory Personnel policy states, a. "All personnel performing laboratory testing will be evaluated for competency on an annual basis, as well as prior to performing unsupervised laboratory testing for the first time. b. New hires will be evaluated for competency upon hire, during their 6th month of consecutive employment, during their 12th month of consecutive employment, and on an annual basis thereafter. c. Competency assessment of testing personnel must include, but are not limited to the following methods: 1. Instrument training based on manufacturer training materials. 2. Direct observation(s) of routine patient test performance, including patient preparation, blood draw, specimen handling, processing and testing. 3. Review of quality control records. 4. Direct observation of performance of instrument maintenance. 5. Assessment of problem-solving skills via written/oral demonstration." 2. Review of laboratory training records found the technical consultant failed to evaluate four out of four testing personnel for competency assessment as described in the laboratory Competency assessment policy for Complete Blood Count (CBC) testing on the CELL-DYN Emerald. a. TP1 initial training on the CELL-DYN Emerald was 12-01-2021 and no competency documented in 2022 through date of survey. b. Testing Personnel two (TP2) initial training on the CELL-DYN Emerald was 12-01-2021 and no competency documented in 2022 through date of survey. c. Testing Personnel three (TP3) initial training on the CELL-DYN Emerald was 07-12-2022 and no competency documented in 2022 through date of survey. d. Testing Personnel four (TP4) initial training on the CELL-DYN Emerald was 01-17-2023 and no competency documented in 2023 through date of survey. 3. On survey date 04-05-2023, at 10:24 am, TP1 confirmed the laboratory uses the CELL-DYN Emerald training checklist for the testing personnel competency assessment form. 4. On survey date 04-05-2023, at 2:45 pm, TP1 confirmed the laboratory technical consultant failed to perform competency assessments for the four testing personnel as outlined in the competency assessment policy.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p>

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of laboratory records and interview with Testing Personnel one (TP1); the laboratory failed to ensure TP1 and Testing Personnel two (TP2) met the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for hematology testing. Findings Include: 1. The laboratory failed to ensure two of four testing personnel were qualified for moderate complexity hematology testing. See D6171.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with Testing Personnel one (TP1); the laboratory failed to ensure TP1 and Testing Personnel two (TP2) were qualified for moderate complexity hematology testing. Findings Include: 1. Review of educational documentation for two of four testing personnel identified on the CMS-209 (Laboratory Personnel Report) failed to meet the educational requirements for moderate complexity testing. a. TP1- no transcripts or diplomas were provided. b. TP2- no transcripts or diplomas were provided. 2. On survey date 04-05-2023, at 11:06 am, the above findings were confirmed by TP1.