

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2104034	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Life Savers Emergency Room	Street Address, City, State 17685 Tomball Parkway, Houston, TX	
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	<p>The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies, allegations of compliance/plans of correction and validation survey response processes were discussed with the laboratory representative(s). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Instructions for Use for the BinaxNOW RSV card, a review of patient test records from December 2022 to January 2023, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by ensuring the BinaxNOW RSV (Respiratory Syncytial Virus) test was run on patients five years of age or older for three of five patient test reports reviewed. Findings include: 1. A review of the Instructions for Use for the BinaxNOW RSV card test</p>

revealed the following: "ATTENTION Do not use the RSV test in patients 5 years or older." 2. A review of the laboratory's patient test records from December 2022 to January 2023 revealed the following 3 patient's samples were run using the BinaxNOW RSV card: Patient ID: 547140 Patient date of birth: 7/6/17 Patient age: 5 years Date tested: 12/20/22 Patient ID: 542271 Patient date of birth: 4/22/13 Patient age: 9 years Date tested: 12/23/22 Patient ID: 857212 Patient date of birth: 8/4/01 Patient age: 21 years Date tested: 1/4/23 3. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/18/23 at 11:20 a.m. in the laboratory, after review of the records, confirmed the above findings.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
 CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
 Based on review of laboratory's proficiency testing (PT) agency instructions, laboratory's PT records for 2022 and staff interview, the laboratory failed to retain PT documents for 2 of 4 reviewed PT events in 2022. Findings included: 1. Review of the laboratory's American Proficiency Institute (API) Proficiency Testing Instructions and Worksheets, and Proficiency Testing Performance Evaluation (Kit # 1 Seq # 2391 and Kit # 1 Seq 5936) revealed: "INSTRUCTIONS FOR REPORTING PROFICIENCY RESULTS ... 7. When testing is finished, keep your documentation (e.g., photocopied worksheets, instrument printouts, online printouts) for your own records. SIGNATURES REQUIRED - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." And, "PERFORMANCE REVIEW AND CORRECTIVE ACTION After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports for your records." 2. Review of laboratory's PT records for 2022 revealed the laboratory did not retain PT records for the following 2 of 4 reviewed 2022 PT events: 2022 Chemistry - Core 2nd Event Tested: 09/09/2022 Failed to retain: kit instructions, worksheets, attestation statements, performance evaluation and forms. 2022 Hematology/Coagulation 3rd Event Tested: 11/20/2022 Failed to retain: kit instructions, worksheets, attestation statements, performance evaluation and forms. 3. In an interview on 04/18/2023 at 1030 hours in the break room, the laboratory's Testing Person number 2 (as described on submitted form CMS-209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D5441

CONTROL PROCEDURES
 CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures

that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy, quality control records from October 2022 to January 2023, patient results, and confirmed in an interview, the laboratory failed to have documentation of monitoring quality control values over time for Quidel Triage Meter Pro analyzer for CKMB, Troponin, Myoglobin, and D-Dimer testing for four of four months reviewed. The findings were: 1. Review of the laboratory's policy titled LEVEY-JENNINGS GRAPHS REVIEW signed by the laboratory director on 12/1/20 revealed "Levey-Jennings graphs will be reviewed weekly. Observations will be documented and corrective actions will be performed to ensure that shifts or trends are corrected." 2. Review of the laboratory's quality control records from October 2022 to January 2023 for Quidel Triage Meter Pro (SN: 00095285WW) revealed no documentation of the laboratory monitoring the quality control values over time for CKMB, Troponin, Myoglobin, and D-Dimer testing for four of four months reviewed. 3. An interview with the technical consultant on 4/18 /2023 at 10:30 am in the laboratory confirmed the above findings. The technical consultant stated the laboratory did not monitor quality control values overtime for Quidel Triage Meter Pro. 4. Random review of the patient results from 11/10/2022 to 2 /27/2023 revealed 56 patients tested on Quidel Triage Meter Pro. 11/10/2022 Sample ID: 1111022950 11/12/2022 Sample ID: 1111222988 11/14/2022 Sample ID: 1111422024 11/14/2022 Sample ID: 1111422040 11/15/2022 Sample ID: 1111522052 11/18/2022 Sample ID: 1111822121 11/22/2022 Sample ID: 1112222182 11/23/2022 Sample ID: 1112322297 11/26/2022 Sample ID: 1112622267 11/27/2022 Sample ID: 1112722316 11/29/2022 Sample ID: 1112922398 12/01/2022 Sample ID: 1120122429 12/03/2022 Sample ID: 1120322489 12/03/2022 Sample ID: 1120322495 12/03/2022 Sample ID: 1120322500 12/07/2022 Sample ID: 1120322564 12/14/2022 Sample ID: 1121422779 12/15/2022 Sample ID: 1121422812 12/20/2022 Sample ID: 1122022952 12/23/2022 Sample ID: 1122322006 12/23/2022 Sample ID: 1122322030 12/25/2022 Sample ID: 1122522075 12/25/2022 Sample ID: 1122522107 12/27/2022 Sample ID: 1122722163 12/30/2022 Sample ID: 1123022248 01/02/2023 Sample ID: 1010223290 01/02/2023 Sample ID: 1010223304 01/05/2023 Sample ID: 1010523415 01/07/2023 Sample ID: 1010723480 01/08/2023 Sample ID: 1010823493 01/11/2023 Sample ID: 1011123555 01/11/2023 Sample ID: 1011123565 01/11/2023 Sample ID: 1011123589 01/18/2023 Sample ID: 1011823713 01/19/2023 Sample ID: 1011823730 01/22/2023 Sample ID: 1012223786 01/25/2023 Sample ID: 1012423818 01/27/2023 Sample ID: 1012723884 01/28/2023 Sample ID: 1012823918 01/28/2023 Sample ID: 1012823912 01/30/2023 Sample ID: 1013023943 02/02/2023 Sample ID: 1020223999 02/02/2023 Sample ID: 1020223013 02/02/2023 Sample ID: 1020223017 02/03/2023 Sample ID: 1020323034 02/03/2023 Sample ID: 1020323048 02/05/2023 Sample ID: 1020423068 02/06/2023 Sample ID: 1020623097 02/10/2023 Sample ID:

	<p>1021023160 02/11/2023 Sample ID: 1021123186 02/16/2023 Sample ID: 1021623270 02/16/2023 Sample ID: 1021623275 02/16/2023 Sample ID: 1021623285 02/17/2023 Sample ID: 1021623285 02/17/2023 Sample ID: 1021723314</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 review of laboratory's policies and procedures, personnel records, patient test records and staff interview, the laboratory's director failed to provide overall direction as evidenced by: 1. The laboratory director failed to ensure all testing personnel had documentation of appropriate education to perform moderate complexity testing. Refer to D6029. 2. The laboratory director failed to ensure all testing personnel's training was completed and staff was competent to perform testing. Refer to D6030.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, laboratory's personnel records and staff interview, the laboratory director failed to ensure all testing personnel had documentation of appropriate education to perform moderate complexity testing. Refer to D6065. Key: CMS - Centers for Medicare and Medicaid</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or</p>

continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies and procedures, personnel training records, patient test records for January 2023 and staff interview, the laboratory director failed to ensure all testing personnel's training was completed and staff was competent to perform testing. Refer to D6053.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies, personnel records and staff interview, the laboratory's technical consultant failed to ensure testing personnel's evaluation and competency were documented at least semiannually during the first year the individual tested patient specimens for 4 of 8 testing personnel employed by the facility. Findings included: 1. Review of laboratory's policy "Technical Consultant Responsibilities" (last reviewed/revised 12/01/2021) revealed: "9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens." 2. Review of laboratory's personnel records revealed the following 4 of 8 testing personnel only had one competency assessment during the first year of testing patient samples: TP (Testing Person) number (as indicated on submitted form CMS-209): 2 Training date: 02/14/2022 Competency assessed: 08/17/2022 Next competency assessment due: February 2023 - not documented TP number: 3 Training date: 02/14/2022 Competency assessed: 07/07/2022 Next competency assessment due: February 2023 - not documented TP number: 4 Training date: 02/16/2022 Competency assessed: 08/16/2022 Next competency assessment due: February 2023 - not documented TP number: 8 Training date: 02/14/2022 Competency assessed: 08/14/2022 Next competency assessment due: February 2023 - not documented 3. In an interview on 04/18/2023 at 1140 hours in the break room, the laboratory's Testing Person number 2 (as indicated on submitted form CMS-209) confirmed that the above competency assessment records were the only evaluation documents for the above personnel (TP 2,3,4 and 8) available for review. Key: CMS - Centers for Medicare and Medicaid

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

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 the laboratory's personnel records and staff interview, the laboratory failed to ensure all testing personnel met the qualification requirements to perform moderate complexity testing. Refer to D6065.

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 the laboratory's personnel records and staff interview, the laboratory failed to ensure 2 of 8 testing personnel had the appropriate education to perform moderate complexity testing. Findings included: 1. Review of the laboratory's personnel records revealed the following 2 of 8 testing personnel (as indicated on submitted Form CMS-209) did not have documentation of appropriate education to perform moderate complexity testing: Testing Person number 5 Hire date: 10/26/2022 Testing Person number 7 Hire date: 06/06/2022 2. In an interview on 04/18/2022 at 1315 hours at the facility's nursing station, the laboratory's Technical Consultant, after being informed of personnel educational requirements, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies and procedures, personnel training records, random patient test records for January 2023 and staff interview, the laboratory failed to document completion of personnel training appropriate for the testing performed prior to analyzing patient specimens for 8 of 8 testing personnel as per its own protocols. Findings included: 1. Review of laboratory's policy "Technical Consultant Responsibilities" (last reviewed/revised 12/01/2021) revealed: "7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed." 2. Review of laboratory's policy "New Procedure Policy" (last reviewed/revised 12/01/2021) revealed: "1) Train testing personnel and document training." 3. Review of laboratory's personnel training records revealed the laboratory used Laboratory Advisory Bureau New Hire Training form to document its personnel's training for each test system used by the laboratory (Medonic CBC

[complete blood count] Analyzer, Abaxis Piccolo Analyzer, Quidel Triage Meter Pro, Clinitek Analyzer (Urinalysis), POC [point of care] tests). This form also included the following statement: "The employee has/ has not completed training on this test system and therefore is/ is not certified to perform this test." 4. Further review of the laboratory's personnel training records revealed that none of the training documents for 8 of 8 testing personnel indicated whether the trainee has or has not completed training, or whether the trainee was or was not certified to perform testing. 5. Review of a random sampling of patient test records for January of 2023 revealed the following test systems were used to perform testing by laboratory personnel whose training was not documented as complete: Date: 01/04/2023 Patient: 617981 Test system used: Medonic CBC, Abaxis Piccolo, Quidel Triage Testing Person number (as indicated on submitted Form CMS-209): 7 Date: 01/04/2023 Patient: 377388 Test system(s) used: POC Testing Person number: 5 Date: 01/05/2023 Patient: 615962 Test system(s) used: Medonic CBC, Abaxis Piccolo, Clinitek, POC Testing Person number: 4 Date: 01/05/2023 Patient: 799320 Test system(s) used: Medonic CBC, Abaxis Piccolo, Quidel Triage Testing Person number: 4 Date: 01/06/2023 Patient: 352769 Test system(s) used: Medonic CBC, Abaxis Piccolo, Quidel Triage, Clinitek, POC Testing Person number: 7 Date: 01/08/2023 Patient: 485894 Test system(s) used: Medonic CBC, Abaxis Piccolo, Clinitek Testing Person number: 7 Date: 01/08/2023 Patient: 354734 Test system(s) used: Medonic CBC, Abaxis Piccolo, Quidel Triage Testing Person number: 7 Note: In many instances testing personnel signatures /initials were illegible and the testing person could not be identified. 6. In an interview on 04/18/2023 at 1150 hours in the laboratory, the Testing Person number 2 (as indicated on submitted Form CMS-209) could not identify the testing personnel's signatures/initials but did confirm that all listed laboratory testing personnel performed testing. Key: CMS - Centers for Medicare and Medicaid