Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0508239	02/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
North Runnels Hospital Laboratory	7821 State Hwy 153, Winters, 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	As a result of the CLIA recertification inspection, the laboratory is not in compliance with the following Conditions of Participation required for certification in the CLIA program at 4 D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;2 CFR part 493:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on review of laboratory policy, proficiency testing records, the CMS-209 laboratory personnel report, and interview with facility personnel, the laboratory failed to include 3 of 6 testing personnel who routinely perform patient testing in proficiency testing for 2018. The findings included: 1. Based on review of the laboratory policy "Proficiency Testing", under Testing Proficiency Samples, the procedures state the following: "Samples are to be tested by personnel who normally perform laboratory testing. Follow the included instructions in the testing packet for specimen preparation needs. These are also available online." 2. Based on a review of proficiency testing records and the CMS-209 laboratory personnel report, all proficiency testing events from the end of 2017 through 3 events in 2018 were performed by Testing Person 1, Testing Person 6, or the Laboratory Director /Technical Consultant: 2017 3rd event Hematology/Coagulation performed by Testing Person 1 2018 1st Event Basic Chemistry performed by Testing Person 1 2018 1st Event Comprehensive Chemistry performed by Testing Person 1 2018 1st event Cardiac markers performed by Testing Person 1 2018 1st event Hematology with Diff A performed by Testing Person 6 2018 1st event Urinalysis performed by Testing Person 6 2018 2nd event Basic Chemistry performed by Testing Person 6 2018 2nd

	event Cardiac Markers performed by Lab Director/Technical Consultant 2018 2nd event Lipids performed by Testing Person 6 2018 2nd event Blood Cell Identification performed by Testing Person 1 2018 2nd event Hematology with Diff A performed by Testing Person 6 2018 2nd event Pregnancy performed by Testing Person 6 2018 2nd event Urinalysis performed by Testing Person 1 2018 2nd event Comprehensive Chemistry performed by Lab Director/Technical Consultant 2018 2nd event Basic Chemistry performed by Lab Director/Technical Consultant 2018 2nd event Cardiac Markers performed by Testing Person 1 2018 3rd event Urinalysis performed by Testing Person 1 2018 3rd event Hematology with Diff A performed by Lab Director /Technical Consultant 2018 3rd event Blood Cell Identification performed by Lab Director/Technical Consultant Testing Persons 2, 3, 4, and 5 did not participate in proficiency testing in 2018. 3. In an interview at 11:00 on 2/19/2019 in the laboratory, the Lab Director stated the lab had not rotated all testing personnel in performing proficiency testing and stated it was challenging for the laboratory because testing persons 2,3,4 and 5 did not work as frequently and predictably as Testing Person 1 and Testing Person 6.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of maintenance records and interview with facility personnel, the laboratory failed to retain documentation of maintenance procedures for 4 of 4 months between January 2018 and April 2018 for the Emerald hematology analyzer and the Dimension EXL chemistry analyzer. 1. In a review of maintenance records at 15:15 hours on 2/19/2019, the surveyor observed the following 4 of 4 months were missing for the Emerald hematology analyzer and the Dimension EXL chemistry analyzer.: January 2018 February 2018 March 2018 April 2018 2. In an interview at 15:29 hours on 2/19/2019 in the laboratory, the Laboratory Manager stated the laboratory could not find the maintenance records for January 2018 through April 2018 and that they were likely in a binder somewhere but couldn't be located at the time of the survey.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the Cell-Dyn Emerald operator's manual, surveyor observations, and interview with facility personnel, the laboratory failed to store 9 of 9 hematology control vials in a central location away from the door in the laboratory refrigerator. The findings included: 1. Based on review of the Abbott Cell-Dyn Emerald operator's manual (09H40-01), on page 11-9, under Quality Control Guidelines, the operator's manual states the following: "Pay particular attention to the following: " Check the

	condition of incoming control material. Be sure that vials are at the proper temperature and are not leaking. Check for hemolysis. " If controls are stored inside a refrigerator, place them in a central location away from the door." 2. At 14:07 hours on 2/19/2019 in the laboratory, the surveyor observed the following 9 of 9 hematology vials stored in the door of the refrigerator: Lot: 8351 Expiration date: 2019 - 04 - 05 3 vials - open and in use, levels 1,2 and 3. 6 vials, unopened and not in use, two vials of level 1, two vials of level 2, two vials of level 3. 3. In an interview at 14:07 hours on 2 /19/2019, the laboratory director stated he was unaware of the requirement in the operator's manual to store the controls in a central location and not in the door.
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: I. Based on review of the Cell-Dyn Emerald operator's manual, review of maintenance records, and interview with facility personnel, the laboratory failed to perform and document required monthly maintenance 8 of 12 months and semi-annual maintenance 1 of 2 6-month periods in calendar year 2018. The findings included: 1. Based on review of the Abbott Cell-Dyn Emerald operator's manual (09H40-01), on page 9-13, under Semi-annual Maintenance, the operator's manual states the following: "Lubricating the Pistons For optimal operation, the Syringe Pistons should be lubricated every six months as described below." and; On page 9-11, the operator's manual states: "Monthly Maintenance: Bleach Cleaning: Clean the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected." 2. Based on review of maintenance records, the laboratory was not able to find documentation of maintenance procedures for 4 months, January 2018, February 2018, March 2018, and April 2018. Refer to D3031. Based on review of maintenance records from May 2018 through December 2018: Monthly maintenance is documented on May 3, 2018. The document the laboratory was using was "Cell-Dyn 3200 Maintenance Log", but the analyzer in use is a different model, the Emerald. The Emerald does not have an auto-clean, but does require a monthly bleaching procedure. Monthly Maintenance is documented as performed on June 28th, 2018. There is no documentation of monthly maintenance for July 2018. Monthly maintenance is documented as performed two times for August 2018 on 8/1/2018 and 8/6/2018. There is no documentation of monthly maintenance for September 2018. The semi-annual "Lube the Pistons" procedure is documented on 9/27/ 2018. Monthly Maintenance is documented as performed on October 19, 2018. There is no documentation of monthly maintenance for November 2018. There is no documentation of monthly maintenance for December 2018. 3. In an interview at 14: 41 hours on 2/19/2019 in the laboratory, the Laboratory manager stated he was not able to find the maintenance records for January through April 2018 and stated some of the maintenance may have been performed on preventative maintenance procedures, but were acknowledged they were not documented on these records. II. Based on review of the chemistry analyzer operator's manual, laboratory maintenance records, and interview with facility personnel, the laboratory failed to perform all of the seven (7) monthly maintenance procedures for 6 of 6 months between August 2018 and January 2019. The findings included: 1. Based on review of the Dimension EXL System Operator's guide, on page 7-8, the manual states the following: "Monthly

	Maintenance Only trained operators should perform these procedures. The seven monthly maintenance procedures are: *Cleaning the Clot Check Drain on the IMT Port * Replacing IMT Pump Tubing * Cleaning the IMT system * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains The replacement procedures use tools and commonly replaced parts that are provided in your Accessory Spare Parts kit. After using a spare part from this kit, be sure to order a new one from Siemens Healthcare Diagnostics." There was no documentation of training for 6 of 6 testing personnel for the Dimension EXL maintenance. Refer to D6045. 2. Based on a review of Dimension EXL maintenance records: Seven (7) of seven (7) monthly procedures were not performed in August 2018 * Replacing IMT Pump Tubing * Cleaning the IMT system * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains Five of Seven procedures were not performed in September 2018: * Replacing IMT Pump Tubing * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains Five of Seven procedures were not performed in October 2018: * Replacing IMT Pump Tubing * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains Five of Seven procedures were not performed in November 2018: * Replacing IMT Pump Tubing * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains Six of Seven procedures were not performed in December 2018: * Replacing IMT Pump Tubing * Cleaning the IMT system * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains Seven (7) of seven (7) monthly procedures were not performed in January 2019 * Replacing IMT Pump Tubing * Cleaning the IMT system * Replacing Instrument Air Filters *Styletting HM Wash Probes * Replacing HM Pump heads on wash station * Cleaning the R2 and R3 drains 3. In an interview at 15:29 hours on 2/19/2019 in the laboratory, the Laboratory Manager stated the laboratory could not find the maintenance records for January 2018 through April 2018 and that the seven monthly maintenance procedures had not been performed each month.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control and calibration records, corrective action records, and interview with facility personnel, the laboratory failed to establish and follow procedures to document all corrective actions and to assess all patients tested in an unacceptable run and since the last acceptable control in 2018. The findings included: 1. Based on review of the laboratory policy "Quality Control", under Corrective Measures for Random and systematic Errors, the document states the following: "DOCUMENT ALL CORRECTIVE ACTIONS TAKEN IN EITHER

	THE QUALITY CONTROL LOG SHEETS OR THE LIS PROGRAM IN THE RESPECTIVE ANALYTE. All control values must fall within the set control limits. If the control values are outside the set limits, the following steps should be taken to evaluate the problem: Check to ensure all preventative maintenance has been performed. Check to ensure the current, calibrated lot of reagent is in use. Rerun the control Make up or open new controls and run them. make up or open new reagent(s) and run test Recalibrate method. Let another technologist make up and run reagents and/or controls Call technical support for the instrument." The corrective action policy does not include instructions for identifying and evaluating all patients tested in the unacceptable run and since the last acceptable quality control to determine if patient test results have been adversely affected. 2. Based on review of analytic records from January 2019, the calibration for LMMB (Creatine Kinase-MB) failed due to an arithmetic error at 11:39 hours on 1/25/2019. The failed calibration was rejected. The LMMB was recalibrated at 12:10 p.m. on 1/25/2019 and the re-calibration was successful. There is no documentation of corrective actions taken regarding the failed calibration. There was no documentation of identifying or evaluating patients tested in the unacceptable run and since the last acceptable run to determine if they were adversely affected. 3. In an interview at 16:26 hours on 2/19/2019 in the laboratory, the Lab Director/Technical Consultant stated that he authored most of the entries on the corrective action log during quality control review and had difficulty getting testing personnel to accurately log the corrective actions taken when calibrations or quality control results were unacceptable.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. This STANDARD is not met as evidenced by: Based on review of testing personnel records and interview with facility personnel, the Laboratory Director failed to ensure 3 of 6 testing personnel had qualifying education documentation prior to performing patient testing and 6 of 6 testing personnel had documentation of the appropriate training for the type and complexity of the services offered by the laboratory. Refer to D6045 and D6065.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(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; This STANDARD is not met as evidenced by:

	Based on review of testing personnel records and interview with facility personnel, the laboratory failed to have documentation of appropriate training for 6 of 6 testing personnel. The findings included: 1. Based on a review of personnel records, 6 of 6 testing personnel did not have documentation of training. 2. In an interview at 08:52 hours on 2/19/2019 in the laboratory, the Laboratory Director stated that each individual was given an in-depth orientation, but no training had been formally documented.
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 personnel education records and interview with facility personnel, the laboratory failed to have documentation of qualifying credentials for 3 of 6 testing personnel. 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 personnel education records and interview with facility personnel, the laboratory failed to have documentation of qualifying credentials for 3 of 6 testing personnel. Refer to D6065. The findings included: Based on review of education credentials for testing personnel, the laboratory did not have qualifying education documentation for 3 of 6 testing personnel: Testing Person 2 In interview with the lab director at 08:46 hours on 2/19/2019, he stated the individual worked weekends, and the lab did not currently have a copy of his diploma. Testing Person 4 In interview with the lab director at 08:46 hours on 2/19/2019, he stated the individual filled in shifts infrequently, and the lab did not currently have a copy of his diploma. Testing Person 5 - In interview with the lab director at 08:46 hours on 2/19/2019, he stated the laboratory had a copy of the degree which was obtained in another country, but did not currently have the foreign equivalency certification documentation. Credential evaluation is the way in which academic and professional degrees earned in one

	country are compared to those earned in another. Universities, colleges and employers around the world use credential evaluations to understand foreign education and to judge applicants for admission or employment.