Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0478993	04/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Nephrology Associates	3604 Live Oak Street Suite 100, Dallas, 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	A recertification survey was conducted 04/14/2021. The laboratory was also surveyed in response to complaint TX00374252 for compliance with CMS 42CFR regulations. Complaint TX00374252 was unsubstantiated. An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 Cobra II Auto Gamma Counting System operator's manual (Publication number 169-4087 Rev. G), laboratory environmental records (01/2020 through 12/2020), and confirmed in interview, the laboratory failed to ensure humidity levels were within operating specifications for the Cobra II Gamma Counter for 12 of 12 months. Findings included: 1. Review of the Cobra II Auto Gamma Counting System operator's manual) stated the following in the section titled "Environmental Requirements": "Relative Humidity: 30-85 percent (noncondensing)" 2. Review of the laboratory environmental logs (01/2020 through 12/2020) titled "Room Humidity Record; Location Glofil Lab" revealed the laboratory utilized a humidity range of greater than 19% and less than 81% for the Glofil Lab. (Note: The Glofil Lab is the location of the Cobra II Auto Gamma Counting instrument.) The humidity range used by the laboratory did not correspond to manufacturer's specified acceptable humidity range of 30-85%. 3. Review of laboratory environmental records (01/2020 - 12/2020) revealed an acceptable humidity range of greater than 19% and less than 81% for the Glofil Lab and the following days when the humidity levels were NOT within manufacturer's operating specifications of 30-85%: 01/06/2020; 28% 01/07/2020; 25% 01/08/2020; 27% 01/09/2020; 28% 01/20/2020; 28% 01/21 /2020; 25% 01/23/2020; 27% 01/24/2020; 23% 01/27/2020; 26% 01/29/2020; 27% 01 /30/2020; 28% 02/03/2020; 21% 02/04/2020; 23% 02/05/2020; 25% 02/06/2020; 22% 02/07/2020; 23% 02/10/2020; 23% 02/11/2020; 23% 02/12/2020; 27% 02/14/2020; 29% 02/20/2020; 27% 02/21/2020; 23% 02/26/2020; 29% 02/27/2020; 27% 02/28 /2020; 29% 04/14/2020; 29% 04/15/2020; 29% 10/26/2020; 25% 10/27/2020; 27% The laboratory failed to ensure acceptable humidity levels were within operating specifications for the Cobra II Gamma Counter. 3. In an interview on 04/14/2021 at 02:59pm in the conference room, after review of the environmental records, the laboratory director and technical supervisor confirmed the above findings.
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, random review of quality control (QC) records, corrective action logs, patient reports, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results for 45 of 45 patients in 2020 (08/2020 and 12/2020) on the Abbott Architect c4000 chemistry analyzer. Findings included: 1. Review of the laboratory's policy "DTI Chemistry Quality Control" (Effective date 03/09/2018) revealed: "The result value of the controls should fall within their established manufacturer's range limits. If not, remedial action should proceed the reporting of test results for all the unknown samples analyzed at that time ...When the control values fall outside of their established range limits, remedial steps are taken to rectify the problem. Patient samples are not to be performed and reported if QC is not acceptable ..." The policy did not include evaluation of patients when test systems adjustments were performed

	for QC failures since the last acceptable QC run. 2. Review of Abbott Architect c4000 chemistry analyzer quality control (QC) records and corrective action logs revealed test system adjustments performed for the following sampling of QC test events in 2020: a. 08/26/2020 Blood Urea Nitrogen (BUN) analyte, Multiqual Control (MQ3) level 3 control lot #56610, expiration date 07/31/2021 Acceptable range: 64.000-72.000 First Correction Action documentation: Corrective action log stated "08/26/20; BUN; Control Level 3; Control Problem Code 1 (code 1 = 1 2s); Repeat Yes, Calibrated Yes; QC still fail" Second Correction Action documentation: Corrective action log stated "08/26/20; BUN; Control Level 3; Control Problem Code 1 (code 1 = 1 2s); Repeat Yes, New reagent Lot#11736UN20-02093" Review of the QC records revealed the following final QC value for the BUN analyte: "Control ID MQ3; Date 08 /26/2020; Time 08:02: Test BUN; Result 71.00; Remark Calibrated" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed: Patient ID#s: 11501467; 11501469; 11501471; 11501473; 11501475; 11501477; 11501479; 11501480; 11501481; 11501482; 11501483; 11501484; 1150478; 11501485; 11501486; 11501488; 11501491; 11501489; 11501493; 11501492; 11501494; 11501496; 11501497; 1150498; 11501500; 11501501; 11501504; 11501503; 11501506; 11501507; 11501508; 11501509; 11501511; 11501513; 11501514; 11501515; 11501516; 11501518; 11501495; 11501499; 11501472; 11501474 b. 12/22/2020 Lipase analyte, Multiqual Control (MQ3) level 3 control lot #56610, expiration date 07 /31/2021 Acceptable range: 135.000 - 159.000 Correction Action documentation: Corrective action log stated "12/22/20; Lipase; Control Level 3; Control Problem Code 2 (code 2 = 1 3s); Repeat Yes, Recalibrated" Review of the QC records revealed the following final QC value for the Lipase analyte: "Control ID MQ3; Date 12/22/20; Time 14:14: Test LIPA (lipase); Result 177.000; Remark Delete Control ID MQ3; Date 12/22/20; Time 14:15: Test LIPA (lipase); Result 178.000; Remark Delete Control ID MQ3; Date 12/23/20; Time 08:17: Test LIPA (lipase); Result 150.000; Remark Calibrated" The following patients were not evaluated to ensure accurate and reliable test results since the last acceptable QC run with test system adjustments performed: Patient ID#s: 11507073; 11507119; 11507140 3. During an interview on 04/14/2021 at 02:05 pm, the Laboratory Director and Technical Supervisor confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results. Word Key: 1 2s = one control measurement within a run exceeds the mean +/- 2 Standard Deviation 1 3s = one control measurement within a run exceeds the mean +/- 3 Standard Deviation