Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0963379	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Nih-Clinical Nephrology Laboratory	Building 10 Room 5-5624, Bethesda, MD	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the policy manual and interview with staff, the laboratory failed to establish written policy and procedure for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general lab system. Findings include: 1. The surveyor reviewed a policy titled "Quality Assessment Plan" signed by the laboratory director on 1/17/18. 2. Within the General Laboratory Section of the policy, there was no section listing ongoing "General Laboratory Assessment". 3. This finding was confirmed during interview with testing personnel at 12:30pm.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the policy manual and interview with staff, the laboratory failed to document the results of assessment activities in the pre-analytic lab system. Findings

	include: 1. The surveyor reviewed a policy titled "Quality Assessment Plan" signed by the laboratory director on 1/17/18. 2. Within the section named 'Pre-Analytic' of the policy on page 4 of the lab's Quality Assessment (QA) Plan stated the following under the bullet 'Pre-Analytic Assessment', "Requisitions are reviewed periodically to detect errors and remedial action is taken as needed." 3. During interview with testing personnel at 12:35pm, there was an admission that while every requisition was checked for accuracy when it arrived in the lab, there was no documentation of such activities.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of records and interview with staff, the laboratory failed to ensure nonwaived high complexity urinalysis (UA) microscopic testing was conducted in a manner that met analytic systems requirements, to include: (1) the procedure manual missing important diagnositic microscopic examination information (D5403); (2) not recording when control materials were received (D5415); (3) using control materials after their expiration date (D5417); (4) with each qualitative procedure, not including a positive and negative control material each day of patient testing (D5449); (5) using commerically assayed control materials assay ranges without verifying the stated values (D5469); (6) using results of control materials without verifying checking results of those materials met the manufacturer's criteria for acceptability before reporting patient results (D5481); (7) not following it's own analytic quality assessment (QA) policy when indicated (D5791) and (8) not documenting the results of it's own analytic QA monitors (D5793). Findings include: See D5403, D5415, D5417, D5449, D5469, D5481, D5791 and D5793.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of the proficiency testing result reports, the procedure manual and interview with staff, the laboratory failed to include definitions for elements seen during the microscopic examination of patient specimens. Findings include: 1. During a review of proficiency testing (PT) results, the surveyor noted an unacceptable result was marked in the survey CAP 2016-CM-B Urine Sediment ID #17 where the lab reported results listed 'Fungi/Yeast' yet the expected answer was 'Bacteria'. 2. The surveyor reviewed the policy titled "Quality Assessment Plan" signed by the lab director on 1/17/18 and noted on page 2 of the policy under the 'Accuracy Tests (PT) and Competency Checks' section stated the following, "Unacceptable events are reviewed and reason for failure is documented on the CAP result form. Steps are taken and documented on the CAP result form to avoid future unacceptable results. All remedial actions are reviewed by the Lab Director, signed and dated on the CAP result form." 3. The surveyor reviewed the procedure titled "Urinalysis, Part 2: Sediment, Manual Microscopic Exam" signed by the laboratory director on 1/17/18 and noted there was no section within this procedure which described how to differentiate between bacteria and fungal elements for testing personnel to follow as a guide. 4. During interview with the testing personnel at 11:45am, there was an admission that the lab did not have anything in writing in its procedure manual to guide testing staff on how to differentiate between bacteria and fungal elements/yeast in patient specimens.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A. Based on review of monthly quality control logsheets, manufacturer's package inserts and staff interview, the laboratory failed to ensure control materials for quantifying urine microscopic cellular materials was not used after their expiration date as expired controls were used during three (December 2016, January 2017 and August 2017) of the last fourteen months reviewed since December 2017. The laboratory reported a total of 475 urine microscopic patient results during those three months. Findings include: 1. Urinalysis quality control (QC) monthly worksheets reviewed for December 2016 indicated MAS Urinalysis Control Level 1, having lot number UA6016111 and expiration date 11/30/16, was analyzed on four (4) dates: 12 /7/16; 12/12/16; 12/19/16 and 12/27/16. During December 2016, a total of 176 urine microscopic patients specimens were read. 2. Urinalysis quality control (QC) monthly worksheets reviewed for January 2017 indicated MAS Urinalysis Control Level 1, having lot number UA6016111 and expiration date 11/30/16, was analyzed on four (4) dates: 01/3/17; 01/9/17; 01/23/17 and 01/30/17. During January 2017, a total of 135 urine microscopic patients specimens were read. 3. Urinalysis quality control (QC) monthly worksheets reviewed for August 2017 indicated MAS Urinalysis Control Level 1, having lot number UA6017071A and expiration date 8/31/17, was

	analyzed on five (5) dates: 8/7/17; 8/11/17;8/14/17; 8/23/17 and 8/28/17. 4. Urinalysis quality control (QC) monthly worksheets reviewed for August 2017 indicated MAS Urinalysis Control Level 3, having lot number UA6017073A and expiration date 8/31 /17, was analyzed on five (5) dates: 8/7/17; 8/11/17; 8/14/17; 8/23/17 and 8/28/17. During August 2017, a total of 164 urine microscopic patients specimens were read. 5. The testing personel stated that they were aware that they were using the MAS Urinalysis control after their expiration date in all three months. B. Based on review of monthly quality control logsheets, manufacturer's package inserts and staff interview, the laboratory failed to ensure they a system was established to document receipt of MAS Urinalysis control materials and other urinalysis supplies were not used when notified of expired, deteriorated or are of substandard quality. Findings include: Cross-reference D5417-A and D5469.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of monthly quality control logsheets, manufacturer's package inserts and staff interview, the laboratory failed to include a positive and negative control material for qualifying urine microscopic cellular materials each day patient specimens were read, to include 16 of 20 days in December 2016, 13 of 17 days in January 2017 and 13 of 18 days in August 2017. The laboratory reported a total of 475 urine microscopic patient results during those three months. Findings include: 1. The laboratory reported 176 patient urine microscopic results in December 2016 when two level of MAS Urinalysis controls was listed as not performed on Dec 1, 2, 7, 8, 9, 13, 14, 15, 16, 20, 21, 22, 23, 28, 29 and 30. 2. The laboratory reported 135 patient urine microscopic results in January 2017 when two level of MAS Urinalysis controls was listed as not performed on Jan 4, 5, 6, 10, 11, 12, 13, 17, 18, 25, 26, 27 and 31 . 3. The laboratory reported 164 patient urine microscopic results in August 2017 when two level of MAS Urinalysis controls was listed as not performed on Aug 1, 2, 8, 9, 13, 14, 15, 16, 17, 18, 24, 25, 29, 30 and 31. 4. During conversation with the testing individual at 12:30pm there was an admission that the facility was only running two levels of MAS Urinalysis controls once per week instead of on each day of patient testing as required.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the

	laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of urinalysis control logsheets, manufacturer's package insert (PI) and interview with staff, the laboratory failed to verify the stated values of commercially assayed urine microscopic controls whenever a new lot number of MAS Urinalysis controls were put into use in the lab on three seperate occassions (Lot # UA6016111 received Jan 22, 2016; Lot # UA6017071A no received date and UA6018011A no received date) for MAS Level 1 and two occassions (Lot #UA6017073A no received date and UA6018043A no received date) for MAS Level 3, between January 2016 and December 2017. Findings include: 1. The laboratory was unaware that the manufacturer's PI (Thermo Scientific) for MAS Urinalysis Controls Levels 1 and 3, stated the following requirement, "Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges." 2. Testing personnel admitted that the laboratory has never verified assayed urine microscopic controls when new lot numbers were received in the laboratory.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of urinalysis control worksheets, manufacturer's PI and interview with staff, the laboratory failed to list acceptable analyte ranges for MAS Urinalysis Level 1 and 3 on its QC Urinalysis worksheets for the following morphologic elements: White Blood Cells, Red Blood Cells and Crystals, on 24/24 monthly worksheets reviewed from January 2016 through December 2017. Findings Include: 1. The laboratory was unaware that the manufacturer's PI (Thermo Scientific) for MAS Urinalysis Controls, Level 1 and 3, listed analyte ranges for microscopic analysis by methodology. 2. Testing personnel stated the lab used the UriSystem methology. 3. MAS Level 1 analyte ranges for Red Cells as 12-80 hpf; White Cells as 12-100 hpf and Crystals as present; MAS Level 3 analyte ranges for Red Cells as 0 hpf; White Cells as 0-5 hpf and Crystals as absent. 4. Testing personnel admitted that the laboratory has never listed manufacturer's analyte range for the UriSystem on its QC Urinalysis logsheets.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of urinalysis quality control worksheets, the lab policies and interview with staff, the laboratory failed to follow procedures in its Quality Assessment Plan when testing personnel identified problems getting new Lot number MAS Urinalysis level 1 and 3 control materials before the old control lot in use expired. This occurred in three seperate months (December 2016, January 2017 and August 2017) within the last 13 months. Findings include: Cross-reference D5417. 1. The lab's Quality Assessment Plan signed by the lab director on 1/17/18 stated in 'Corrective process' on page 2, "When problems arise in controls, equipment, reagents, or any other phase of analysis the testing personnel will: Identify and resolve the problem; Monitor corrective actions to ensure prevention of recurrence; Develop policies that will prevent the reoccurance; Communicate written policies to all staff and document all Quality Assessment activities." 2. Testing personnel stated that they had notified the lab director of the problems with not having received new lot of MAS Control material prior to the old lot number expiring on several occassions and nothing was done.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A. Based on review of urinalysis quality control worksheets, the lab policies and interview with staff, the laboratory failed to follow procedures in its Quality Assessment Plan when testing personnel identified problems getting new Lot number MAS Urinalysis level 1 and 3 control materials before the old control lot in use expired. This occurred in three seperate months (December 2016, January 2017 and August 2017) within the last 13 months. Findings include: Cross-reference D5417. 1. The lab's Quality Assessment Plan signed by the lab director on 1/17/18 stated in 'Corrective process' on page 2, "When problems arise in controls, equipment, reagents, or any other phase of analysis the testing personnel will: Identify and resolve the problem; Monitor corrective actions to ensure prevention of recurrence; Develop policies that will prevent the reoccurance; Communicate written policies to all staff and document all Quality Assessment activities." 2. Testing personnel stated that they had notified the lab director of the problems with not having received new lot of MAS Control material prior to the old lot number expiring on several occassions and there was an admission that this problem was not documented as stated in the QA Plan. B. Based on review of the policy manual and interview with staff, the laboratory failed to document the results of assessment activities in the analytic lab system. Findings include: 1. The surveyor reviewed a policy titled "Quality Assessment Plan" signed by the laboratory director on 1/17/18. 2. Within the section named 'Analytic' of the policy on page 6 of the lab's Quality Assessment (QA) Plan stated the following under the bullet 'Pre-Analytic Assessment', "A review of the analytic system is perform annually. All maintenance and control documents are reviewed for completeness." 3.

	During interview with testing personnel at 12:40, there was an admission that no documentation of such activities was performed. 4. Cross-reference D6093 and D6117.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the policy manual and interview with staff, the laboratory failed to establish written policy and procedure for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general lab system. Findings include: 1. The surveyor reviewed a policy titled "Quality Assessment Plan" signed by the laboratory director on 1/17/18. 2. Within the Post-Analytic Section of the policy on page 6, there was no "Post-Analytic Assessment" stated. 3. This finding was confirmed during interview with testing personnel at 12:30pm.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of records and interview with laboratory director, the director failed to provide overall management and direction with requirements within this subpart, that included failing to: (1) identify problems when proficiency testing (PT) reports received were reviewed by hmself (D6091); (2) write an approved corrective action plan when any PT result was found to be unacceptable or unsatisfactory (D6092); (3) maintain the quality control, (D6093); (4) pre-analytic, and analytic quality assessment programs (D6094) and (5) maintain acceptable levels of analytic quality (D6095), that ensured high complexity urinalysis (UA) microscopic testing was conducted in a manner that ensured accurate and reliable patient test results. Finding include: See D6091, D6092, D6093, D6094 and D6095.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the proficiency testing result forms, the procedure manual and interview with the lab director, the director failed to ensure all proficiency testing report received that indicated problems that required corrective action were identified

	during reviews of the reports. Findings include: Cross-reference D5403. 1. During a review of proficiency testing (PT) results, the surveyor noted an unacceptable result was marked in the survey CAP 2016-CM-B Urine Sediment ID #17 where the lab reported results listed 'Fungi/Yeast' yet the expected answer was 'Bacteria'. 2. An examination of the CAP PT result form indicated that the lab director signed off on the results as reviewed on 10/19/2016 and there was no annotation that the reviewer of the results acknowledged the failure and documented the results of corrective action taken to determine why the failure occurred on the CAP result form as stated in the QA Plan (See D5403). 3. During interview with the lab director at 12:50am, there was an admission that while he did review each CAP event PT result form, he also admitted to having missed the need to acknowledge the unacceptable result in CAP 2016 CM-B Specimen #17 in writing.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing result forms, the procedure manual and interview with the lab director, the director failed to ensure all proficiency testing report received that indicated problems that required corrective action were identified during reivews of the reports. Findings include: Cross-reference D5403. 1. During a review of proficiency testing (PT) results, the surveyor noted an unacceptable result was marked in the survey CAP 2016-CM-B Urine Sediment ID #17 where the lab reported results listed 'Fungi/Yeast' yet the expected answer was 'Bacteria'. 2. An examination of the CAP PTevent summary result form for 2016 CM-B showed no documentment of an approved corrective action taken to determine why the failure occurred as stated in the QA Plan (See D5403). 3. During interview with the lab director at 12:55am, there was an admission that, while he was aware testing personnel incorrectly identified Fungi/yeast for bacteria in Specimen #17, he admitted that he must have missed the need to record the corrective action taken by the laboratory to prevent the error from reoccurring.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of monthly Urinalysis quality control logsheets, manufacturer's PI and interview with staff, the laboratory director failed to establish and maintain a quality control program that ensured acceptable levels of analytic performance in the UriSystem examination of urine sediment by manual microscopy method. Findings include: Cross-reference D5417, D5449, D5469 and D5481.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	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. This STANDARD is not met as evidenced by: Based on review of monthly Urinalysis quality control logsheets, laboratory procedures and interview with staff, the laboratory director failed to establish and maintain a quality assessment program that ensured quality examinations of patient urine sediments and identified failures in that quality as they occurred. Findings include: Cross-reference D5291, D5391, D5791, D5793 and D5891.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of monthly Urinalysis quality control (QC) logsheets, manufacturer's PI and interview with staff, the laboratory director failed to ensure the quality control program established for the UriSystem examination of urine sediment by manual microscopy method was maintained through periodic review of monthly Urinalysis QC logsheets. Findings include: Cross-reference D5417, D5449, D5469 and D5481.