| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 33D2101355 | 07/10/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| North Shore Hematology-Oncology Associates Pc | 72 East Main Street, Babylon, NY | |

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 |
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| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the manufacturer's packet insert for Siemens Multistix, review of the laboratory's policy manual, and interview with the two laboratory QA Associates, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative Quality Controls (QC) with each new vial opened for the urine Multistix and failed to follow the laboratory's QC policy..<br>FINDINGS: 1. The laboratory is using Siemens Multistix. The packet insert for the urine Multistix requires that external controls be performed with each new Vial of Multistix opened. The laboratory's QC policy requires that external positive and negative QC to be tested daily. 2. On July 10, 2019 at approximately 11:00 AM the laboratory QA Associates confirmed surveyor's findings that documentation for the required external control testing was not available for the lot # 601027 expiration date 06/2017, lot # 510019 exp date 03/2017, lot # 601038 exp date 07/17 and lot # 708043 exp date 2/28/2019. 3. The QC log for urinalysis for the calendar year 2017 indicated that the external QC was tested once on 3/7/17 and once on 9/28/17. 4. Approximately 300 patients specimens were tested and reported for urinalysis using the above vial Multistix. 5. The QC log for urinalysis for the calendar year 2017 indicated that laboratory failed to discontinue the use of the expired Multistix. The laboratory opened a vial of Multistix on 6/6/17 lot # 601038 exp date 07/17. The next Multistix vial was opened on 12/27/17. The laboratory used expired Multistix from 08/2017 through 12/26/17. 6. Approximately 50 patients specimens were tested and reported for urinalysis during the above time frame. |
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| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor's review of the personnel files and interview with the two laboratory QA Associates, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for the one of four testing persons in calendar year 2018. |