| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D2116513 | 07/11/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Urgent Specialists, Llc Dba Urgent Specialists | 2120 W Ina Rd, Ste 100, Tucson, AZ | |

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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| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) documentation, review of patient test reports and interview with the technical consultant, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on the Sysmex pocHi-100i analyzer, with an approximate annual test volume of 1,000. The CBC test performed by the laboratory includes a 3-part differential including Neutrophils, Lymphocytes and Mixed cells which are reported in both percentages and actual numeric values. 2. Review of the test report for patient# 004633 performed on 01/23/2018 indicated the following differential test results: Lym% = 33.6%, Mxd% = *000, Neut% = *000, Lym# = 3.0 (10*3/uL), Mxd# = *000, and Neut# = *000. The WBC value for this patient was 8.9 (10*3/uL) and the instrument generated a "T2" alarm code for the WBC result as noted on the test report. According to the instrument manufacturer, the T2 alarm is defined as a Histogram alert. 3. The technical consultant stated that testing was performed only one time on the specimen indicated above and the test results were scanned into the patient's EMR as the final test report. 4. No documentation was presented for review during the survey to indicate the laboratory established a policy or procedure for testing personnel to follow in the event that the analyzer does not generate a value or result for each analyte tested and reported in a CBC test, including how to identify whether or not the specimen is compromised or if |

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| | further testing is required. 5. The technical consultant confirmed that the laboratory failed to have an established policy and procedure in place to identify potential testing and/or sample errors for testing performed on the pocHi-100i analyzer. |