| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 04D2150843 | 04/17/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Healthcare Express - Sherwood | 1554 Country Club Rd, Sherwood, AR | |

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 |
|---|---|
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Through review of the manufacturer's instrument user's manual, laboratory records of room humidity, technical consultant's quality assurance memoranda and interview it was determined that the laboratory's corrective action to establish the required room humidity was not effective on seventeen of thirty days of operation in March 2019. Findings follow: A. Review of the manufacturer's supplied user's manual for the Sysmex XP 3000 hematology analyzer revealed that the required operational humidity level was 30% to 80%. B. Review of the laboratory's room humidity records revealed that the the room humidity was recorded as less than 30% on seventeen of thirty-one days in January of 2019. C. Review of the technical consutant's quality assurance memorandum for February 2019 revealed that "humidity was documented as less than 30%", and "humidifier may have to be used". D. Review of the laboratory's room humidity records revealed that the the room humidity was recorded as less than 30% on seventeen of thirty days in March of 2019. E. In an interview on 4/17/19 at approximately 12:00 PM, the technical consultant, identified as number 3 on the CMS 209 form, and the testing personnel, identified as number 4 on the CMS 209 form, confirmed that the corrective action identified on the technical consultant's quality assurance memorandum on February 2019 was not effective. |