Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0896920	05/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Uams Regional Programs Jonesboro	311 E Matthews Ave, Jonesboro, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of Celldyne 1800 data logs, quality control reports, lack of documentation and interview it was determined that the laboratory reported patient CBC (complete blood cell count) results without performing required quality control on one of 18 days of operation in July 2017. Findings follow: A. Review of Celldybe 1800 data log revealed that complete blood cell counts were performed and reported on patient 431497247 and patient 76702 on Monday, 07/28/17 with no evidence of quality control being performed on that day. B. Review of the quality control report for July 2017 revealed no evidence of quality control being peformed on 07/28/17. C. Upon request, the laboratory was unable to produce a record of quality control procedures being performed on 07/28/17. B. In an interview on 05/09/18 at aproximately 1600 the technical consultant identified as number 2 on the CMS 209 form confirmed that CBC's were run and reported on 07/28/17 without the required quality control being performed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)

	(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Through review of laboratory quality control reports, the laboratory's policy and procedure for quality control, the laboratory's Remedial (Corrective) Action Log, lack of documentation and interview it was determined that the laboratory failed to document corrective action on one of one occasions of quality control results failing to meet acceptable limits in November of 2017. Findings follow: A. Review of the laboratory's policy and procedure for complete blood cell counts revealed that quality control results are unacceptable if two of three quality control results are outside of the define acceptable limits for any test in a complete blood cell panel. B. Review of the quality control report for November 27, 2017 revealed that normal control for platelet count (lot# 61709-12) with acceptable limits of 208 to 258 were resulted as 267 at 08:51 AM, 273 at 08:53 AM, 262 at 08:55 AM before an acceptable level of 249 at 09:02 AM. C. Review of the quality control report for November 27, 2017 revealed that high control for platelet count (lot# 31709-13) with acceptable limits of 455 to 545 were resulted as 550 at 08:55 AM, 554 at 08:56 AM and 572 at 09:06 AM with no result within acceptable limits. D. Review of the Remedial (Corrective) Action Log for November 2017 revealed that there was no entry for November 27, 2017. E. In an interview on 5/9/17 at approximately 1600, the technical consultant identified as number 2 on the CMS 209 form confirmed that no corrective action was documented on November 27, 2017.