

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0939043	(X3) Date Survey Completed 05/22/2018
Name of Provider or Supplier Mercy Laboratory Services - Highway 102	Street Address, City, State 3101 Se 14th Street, Bentonville, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Through review of the "Mercy Medical Clinics Physician Office Lab Quality Assessment: Issue Resolution Flow" report dated 09/27/17, quality control reports, lack of documentation and interview it was determined that the laboratory failed to retain quality control records for one of one instance of quality control failure due to instrument malfunction of the Sysmex Hematology analyzer. Findings follow: A: Review of the "Mercy Medical Clinics Physician Office Lab Quality Assessment: Issue Resolution Flow" report dated 9/27/17 revealed: 1) At 6:07 PM on 9/21/17 the laboratory reported results at a critical level for a patient who was then referred to the hospital and subsequently the test results were determined to be within normal range by the hospital. 2) On the morning of 9/22/17 the quality control results for the Sysmex hematology analyzer were outside of acceptable range. 3) On 9/22/27 the service representative for Sysmex was called and discovered and repaired a "broken sample probe" on the Sysmex hematology analyzer and subsequent quality control results were within acceptable range. B: Review of the laboratory's quality control summary report for September 2017 revealed quality control results that were outside of acceptable range on September 22, 2017, as revealed on the "Mercy Medical Clinics Physician Office Lab Quality Assessment: Issue Resolution Flow", were not documented on the summary report. C: Upon request, the laboratory was unable to provide an instrument print-out or other documentation of quality control results performed on the morning of 9/22/17 that were outside of acceptable limits. D: In an</p>

interview on 5/22/17 at approximately 1530, the technical consultant identified as number 9 on the CMS 209 report confirmed that the unacceptable quality control results from the morning of 9/22/17 were not available and must have been deleted.