

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2100807	(X3) Date Survey Completed 02/01/2018
Name of Provider or Supplier Bahr Dermatology Pc	Street Address, City, State 25 West 500 South, Bountiful, UT	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on twice annual verification record review, lack of documentation, and interview with staff, the laboratory failed to verify histopathology test accuracy at least twice a year for 1 of 2 years of testing reviewed, (2017). The laboratory performed approximately 100 frozen section cases per year. Findings include: 1. Test accuracy record reviewed failed to include documentation the laboratory verified histopathology frozen section test accuracy verification at least twice annually in 2017. 2. In an interview conducted on 02/01/2018 at approximately 9:45 A.M. staff confirmed the laboratory had not performed the verification on 2 separate occasions in 2017. Staff stated they sent cases performed in 2017 for verification in January 2018.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
Based on patient test reports review, lack of documentation and interview with staff, the laboratory failed to include the case/slide number on the frozen section (Mohs surgery) report for 1 of 9 case reports reviewed. Findings include: 1. Patient test report for Mohs frozen section case 16M-032 failed to include the slide numbers which are the same as the case number on the test report. 2. In an interview with staff on 02/01/2018 at approximately 10:00 A.M. staff confirmed the slide/case number was not included on the test report.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on quality assessment (QA) monthly evaluation documentation review, lack of documentation, and interview with staff, the director failed to ensure the laboratory maintained their quality assessment program to document they evaluated general laboratory, pre-analytic, analytic, and post analytic quality assessment monitoring for two years of testing reviewed (February 2016 to February 2018). Findings include: 1. The laboratory quality assessment plan stated the laboratory process for monitoring specimen acceptance, specimen diagnosis accuracy, stain and histology specimen quality, and test report completion was to record they monitored quality measures monthly. 2. The laboratory failed to record monthly evaluation of quality assessment activities and performed twice yearly test accuracy checks in 2017. (See D5217). 3. In an interview with staff on 02/01/2018 at approximately 9:45 A.M. staff confirmed they had not kept up with monthly QA documentation from February 2016 to February 2018..