

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1094440	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Advanced Dermatology & Skin Cancer Center	Street Address, City, State 1444 E Stearns St, Suite 11, Fayetteville, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of 2016 and 2017 American Proficiency Institute(API) proficiency testing results, it was determined the laboratory failed to have successful participation in proficiency testing in the subspecialty of Mycology as evidence by: Failure to achieve an overall testing event score of satisfactory performance in three of four consecutive testing events is unsuccessful performance as cited at D2046.</p>
D2017	<p>REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)</p>

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:
Based on review of American Proficiency Institute (API) testing results, and interviews with laboratory staff, it was determined the laboratory had a subsequent unsuccessful performance for the subspecialty of Mycology (Dermatophyte Identification) as evidenced by: Failure to achieve satisfactory performance for the subspecialty of Mycology (Dermatophyte Identification) in three out of four consecutive testing events, as cited at D2046.

D2046

MYCOLOGY
CFR(s): 493.827(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on the review of the 2016 and 2017 American Proficiency Institute(API) proficiency testing results it was determined the laboratory had three out of four consecutive failures which constitutes unsuccessful performance for the subspecialty of Mycology (Dermatophyte Identification) as evidenced by: A. The laboratory received an overall score of 60% in the third proficiency testing event of 2016, 60% in the first proficiency testing event of 2017, and 60% in the third proficiency testing event of 2017 for subspecialty of Mycology (Dermatophyte Identification). B. In an interview at 11:28 on 1/11/2017, the laboratory technical consultant confirmed three of four proficiency test failures for Mycology (Dermatophyte Identification).

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of 2016 and 2017 proficiency testing reports, it was determined the laboratory director failed to ensure that corrective action was effective and failed to

provide overall management and direction as cited at: D6019 - Failure to ensure that corrective action was effective. D6032 - Failure to specify, in writing, the procedures each testing person can perform and whether supervision is required

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of 2016 and 2017 proficiency testing scores, it was determined the laboratory director failed to ensure the correction action followed for the unsatisfactory performance for the subspecialty of Mycology (Dermatophyte Identification) corrected the problem. As Cited at D2046.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Through a review of personnel files for the three testing personnel listed on the CMS-209 form as well as interviews with staff, it was determined the laboratory director failed to specify, in writing, the procedures each testing person can perform and whether supervision is required. Survey findings follow: A. In an interview with the laboratory technical consultant, (11:12 on 1/11/2018) he stated that the three testing personnel listed on the form CMS-209 as employee #2, #3 and #4 perform KOH and Wet Prep procedures. B. Through a review of testing personnel employment files it was revealed that three of three personnel files lacked documented authorizations to perform KOH and Wet Prep examination. C. In an interview with the laboratory technical consultant, (11:12 on 1/11/2018) he confirmed the laboratory director failed to give written authorization for employee #2, #3, and #4 to perform KOH and Wet Prep procedures without direct supervision.