

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0165599	(X3) Date Survey Completed 05/09/2019
Name of Provider or Supplier Kate S Robinson Md Pllc	Street Address, City, State 6851 East Genesee Street, Fayetteville, NY	
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 surveyor's review of the College of American Pathologists (CAP) Proficiency Testing (PT) program records and an interview with the Nurse Practitioner (NP) and testing person, the laboratory failed to participate and perform successfully in a PT program, for the subspecialty Bacteriology/Throat Culture. The following scores were assigned: 2018 third event = 0% [failure to participate] 2019 first event = 0% [failure to participate] This is considered unsuccessful PT performance [failure to participate]. Refer to D2028.</p>
D2028	BACTERIOLOGY

CFR(s): 493.823(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 surveyor's review of the CAP PT program and an interview with the NP and testing person, the laboratory failed to participate and perform successfully in a PT program, for the subspecialty Bacteriology/Throat Culture. The following scores were assigned: 2018 third event = 0% [failure to participate] 2019 first event = 0% [failure to participate] This is considered unsuccessful PT performance [failure to participate].

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the NP and testing person, at the time of this survey, the laboratory failed to follow their established QA policy and perform a annual QA review for the 2017 and 2018 calendar years. FINDINGS: The NP and testing person confirmed on May 9, 2019 at approximately 11:00 AM, the laboratory failed to follow their established written QA policy and perform an annual QA review in 2017 and 2018 to include all laboratory systems: patient confidentiality; specimen identification and integrity; complaint investigations; communications; personnel competency; and proficiency testing performance/comparison testing. THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 28, 2017.

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 the surveyor's review of laboratory records and an interview with the NP and testing person, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure that: That the plan of correction from the survey conducted on April 28, 2017 was implemented and maintained. 1. The laboratory achieved a satisfactory performance and successfully participate in a PT program, for the subspecialty Bacteriology for the 3rd event of

2018 and 1st event of 2019 PT events, refer to D6016; 2. The general laboratory systems QA reviews were performed annually, refer to D6021. THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 24, 2017.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's CAP PT records and an interview with the NP and testing person, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the subspecialty Bacteriology/Throat Culture. The following scores were assigned: 2018 third event = 0% [failure to participate] 2019 first event = 0% [failure to participate] This is considered unsuccessful PT performance [failure to participate].

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 surveyor's review of the laboratory QA policy, and on lack of the QA records, and confirmed in a interview with the NP and testing person, the laboratory director failed to ensure that the general laboratory systems QA reviews were performed annually, as required by their QA policy, in calendar year 2017 and 2018. Refer to D5291. THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON APRIL 24, 2017.