

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0348903	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Wright State Physicians	Street Address, City, State 1222 S Patterson Blvd, Suite 210, Dayton, OH	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Practice Manager (PM), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of an ongoing mechanism to monitor, assess, and correct problems identified in the general laboratory systems. Findings Include: 1. Review of the laboratory's "Policy and Procedures" manuals provided on the second meeting for the inspection at the Ohio Department of Health, found no mention of general laboratory quality assessment. 2. The Surveyor requested the laboratory's quality assessment policy and procedure to include the general laboratory systems and 2016, 2017 and 2018 general laboratory systems quality assessment documentation from the PM. The PM confirmed the laboratory did not have any quality assessment policy and procedure established, and did not document any quality assessment activities, and was unable to provide the requested documentation on the date of the second meeting. The interview occurred on 03/15/2018 at 11:15 AM.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p>

This STANDARD is not met as evidenced by:
Based on record review and an interview with Practice Manager (PM), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the preanalytic systems. Findings Include: 1. Review of the laboratory's "Policy and Procedures" manuals provided on the second meeting for the inspection at the Ohio Department of Health, found no mention of general laboratory preanalytic quality assessment. 2. The Surveyor requested the laboratory's preanalytic quality assessment policy and procedure to include the general laboratory systems and 2016, 2017 and 2018 preanalytic general laboratory systems quality assessment documentation from the PM. The PM confirmed the laboratory did not have any preanalytic quality assessment policy and procedure established, and did not document any preanalytic quality assessment activities, and was unable to provide the requested documentation on the date of the second meeting. The interview occurred on 03/15/2018 at 11:15 AM.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on record review and an interview with Practice Manager (PM), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the postanalytic systems. Findings Include: 1. Review of the laboratory's "Policy and Procedures" manuals provided on the second meeting for the inspection at the Ohio Department of Health, found no mention of general laboratory post analytic quality assessment. 2. The Surveyor requested the laboratory's post analytic quality assessment policy and procedure to include the general laboratory systems and 2016, 2017 and 2018 post analytic general laboratory systems quality assessment documentation from the PM. The PM confirmed the laboratory did not have any post analytic quality assessment policy and procedure established, and did not document any post analytic quality assessment activities, and was unable to provide the requested documentation on the date of the second meeting. The interview occurred on 03/15/2018 at 11:15 AM.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based upon a review of proficiency testing records from the College of American Pathologists (CAP), used to assess twice annual accuracy verification, and staff interview, the laboratory failed to review all proficiency results by appropriate staff.

Findings were as follows: 1. The following proficiency survey records contained no evidence of review of proficiency test results: CRS-A 2017 Crystals - Final test results not reviewed/signed by laboratory director or their designee. No evidence that the testing person and laboratory supervisor signed the test results report. CM-B 2017 Clinical Microscopy - Final test results not reviewed/signed by laboratory director or their designee. No evidence that the testing person and laboratory supervisor signed the test results report. CRS-B 2017 Crystals - Final test results not reviewed/signed by laboratory director or their designee. No evidence that the testing person and laboratory supervisor signed the test results report. 2. The above findings were confirmed by interview with the Practice Manager on 03/15/2018 at 10:31 AM.