

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0710807	(X3) Date Survey Completed 03/03/2020
Name of Provider or Supplier American Health Network Of In, Llc	Street Address, City, State 10649 Bennett Parkway, Zionsville, IN	
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 record review and interview, the laboratory failed to perform twice annual verification of accuracy for KOH (potassium hydroxide) tests performed in 2018 and 2019 for six of six test reports reviewed. Findings include: 1) Upon request for review of twice annual verification of PPM procedures for 2018 and 2019, SP-1 confirmed none was available. 2) Record review indicated the following patients had PPM procedures (KOH) performed in 2018: PT=patient PT Date Result a) PT#1 3-31-18 Negative b) PT#2 6-12-18 Positive c) PT#3 4-9-18 Positive d) PT#4 5-4-18 Positive e) PT#5 6-4-18 Positive f) PT#6 4-12-18 Positive 3) In interview on 3/3/20 at 1:47 pm, SP-1 confirmed there was no twice annual verification of accuracy performed or documented for 2018 and 2019. 4) Annual PPM testing is approximately, 1.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to provide a procedure manual for KOH (potassium hydroxide) for six of six test reports reviewed.</p>

Findings include: 1) Upon request for KOH policies/procedures, SP-1 confirmed none were available for review. 2) Record review indicated the following patients had KOH performed in 2018: PT=patient PT Date Result a) PT#1 3-31-18 Negative b) PT#2 6-12-18 Positive c) PT#3 4-9-18 Positive d) PT#4 5-4-18 Positive e) PT#5 6-4-18 Positive f) PT#6 4-12-18 Positive 3) In interview on 3/3/20 at 12:10 pm, SP-1 confirmed there were no KOH policies/procedures available for review. 4) Annual PPM testing is approximately, 1.