

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1045688	(X3) Date Survey Completed 01/31/2019
Name of Provider or Supplier John Cottam Md Pa	Street Address, City, State 14310 N Dale Mabry Ste 180, Tampa, FL	
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 review of policy and procedures, lack of documentation, and interview with the Office Manager, the laboratory failed to ensure the accuracy and precision of reading Gomori Methenamine Silver Nitrate (GMS) stains, and SOX 10 stains (SOX 10 is a member of the sex determining region Y and related box 10 family. SOX 10 is a marker for melanoma) twice a year for for one out of one year (2018) reviewed in the specialty of Histopathology. Findings Included: A review of the policy titled "Proficiency Testing Self Assessment" states that " 5-10 slides every three month's of routine caseload are to be reviewed by quality control pathologists". The policy does not state what slide stains would be sent out to the quality control pathologists. Review of the Quality Control log revealed that GMS testing had started in 03/23 /2018 and SOX 10 testing had started 04/11/2018. The " Proficiency Testing Self Assessment" documentation for 2018 was requested and provided. The forms lacked documentation of what type of slide stains were present. Interview on 01/31/2019 at 12:20 PM confirmed that the laboratory had not pulled twice annually slides for the GMS stain or SOX 10 stain for the 2018 "Proficiency Testing Self Assessment".</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The</p>

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to check the Gomori Methenamine Silver Nitrate (GMS) stain and SOX 10 stain negative control each time of use and failed to document the reactivity of the negative and positive control slides for one out of one year (2018) reviewed in Pathology. Findings included: Quality Control record review revealed that GMS testing had started 03/23/2018 and SOX testing had started 04/11/2018. Quality Control record review for GMS and SOX stain test results revealed documentation for one quality control (the positive) was run with each stain. GMS slides were read on the following days: 03/23/2018 - 2 patients 03/30/2018 - 2 patients 03/29/2018 - 1 patient 04/12/2018 - 1 patient 04/19/2018 - 2 patients 05/23/2018 - 1 patient 05/31/2018 - 1 patient 06/05/2018 - 1 patient 06/21/2018 - 2 patients 06/25/2018 - 3 patients 07/12/2018 - 1 patient 08/24/2018 - 1 patient 12/14/2018 - 1 patient SOX 10 slides were on the following days: 04/09/2018 - 2 patients 04/12/2018 - 1 patient 04/18/2018 - 1 patient 04/19/2018 - 3 patients 04/26/2018 - 1 patient 04/27/2018 - 1 patient 04/30/2018 - 1 patient 05/02/2018 - 1 patient 05/03/2018 - 1 patient 05/08/2018 - 1 patient 05/10/2018 - 1 patient 05/15/2018 - 1 patient 05/18/2018 - 3 patients 05/21/2018 - 1 patient 05/22/2018 - 1 patient 05/25/2018 - 1 patient 05/31/2018 - 1 patient 06/05/2018 - 3 patients 06/11/2018 - 3 patients 06/12/2018 - 1 patient 06/20/2018 - 2 patients 06/21/2018 - 1 patient 06/29/2018 - 1 patient 07/06/2018 - 2 patients 07/13/2018 - 2 patients 07/17/2018 - 1 patient 08/07/2018 - 1 patient 08/08/2018 - 1 patient 08/17/2018 - 2 patients 08/22/2018 - 3 patients 08/27/2018 - 1 patient 08/29/2018 - 1 patient 09/01/2018 - 1 patient 10/01/2018 - 2 patients 10/05/2018 - 4 patients 10/15/2018 - 2 patients 10/17/2018 - 1 patient 11/06/2018 - 1 patient 11/08/2018 - 1 patient 11/13/2018 - 1 patient 11/14/2018 - 1 patient 11/28/2018 - 1 patient 11/29/2018 - 1 patient 12/06/2018 - 1 patient 12/07/2018 - 1 patient 12/19/2018 - 1 patient 12/20/2018 - 1 patient 12/21/2018 - 2 patients 01/11/2019 - 1 patient 01/17/2019 - 2 patients 01/21/2019 - 1 patient 01/22/2019 - 1 patient Interview on 01/31/2019 at 11:30 AM with the Office Manager confirmed that the laboratory did not run a negative control with the GMS and SOX stains and did not document the reactivity of the negative and positive quality controls. (SOX 10 is a member of the sex determining region Y and related box 10 family. SOX 10 is a marker for melanoma)