

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2238486	(X3) Date Survey Completed 05/24/2022
Name of Provider or Supplier Peak Gastroenterology Associates, Inc	Street Address, City, State 3495 Hacks Cross Road, Suite 102, Memphis, TN	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, record request, patient records, and interview with the laboratory liaison, the laboratory failed to follow its' own safety procedures for monitoring employees for exposure to xylene and formalin from 11/04/2021 to the date of the survey on 05/24/2022. The findings include: 1. Observation of the laboratory on 05/24/2022 at 9 am revealed xylene and formalin in use for performing histopathology specimen processing. 2. Review of the laboratory procedure titled "Formalin/Formaldehyde and Xylene Safety" under the section titled" B. Exposure Monitoring" revealed the following statement: "Initial monitoring will be performed in areas where there is potential for employees to be exposed at or above the Action Level or at or above the STEL." 3. A request made to the laboratory liaison on 05/24/2022 at 9 am for exposure monitoring records revealed no records were available. 4. Review of the first patient processed in the laboratory revealed patient specimen processing began on 11/04/2021. 5. Interview with the laboratory liaison on 05/24/2022 at 12 pm confirmed the laboratory began testing/processing patient specimens on 11/04/2021 and did not perform monitoring for exposure to xylene and formalin when patient testing began in 2021 until the survey date on 05/24/2022.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the laboratory liaison, the laboratory failed to label chemicals and stains with lot numbers and expiration dates in 2022. The finding include: 1. Observation of the laboratory on 05/24/2022 at 9 am revealed multiple chemicals and stains in use for processing and staining patient tissue for histopathology procedures that were not labeled with lot number, preparation dates and expiration dates. 2. Interview with the laboratory liaison on 05/24/2022 at 9 am confirmed chemicals and stains in use for patient histopathology tissue processing and staining were not labeled with lot numbers and expiration dates on the date of the survey (05/24/2022).

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(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 laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient test reports, record request, and interview with the laboratory liaison, the laboratory failed to document hematoxylin and eosin stain quality assessment for five of five selected dates in 2021 and 2022. The findings include: 1. Observation of the laboratory on 05/24/2022 at 9 am revealed processing and staining of tissue for histopathology using hematoxylin and eosin stains (H&E). 2. Review of randomly selected patient test reports/dates revealed patient histopathology cases reported as follows: TGJ21-0238-0000002--reported on 11/08/2021 TGJ21-0238-0000526--reported on 12/13/2021 TGJ22-0238-0000381--reported on 01/27/2022 TGJ22-0238-0001555--reported on 04/01/2022 TGJ22-0238-0002457--reported on 05/12/2022 3. Request made to the laboratory liaison on 05/24/2022 at 11 am for H&E stain quality assessment records revealed no records were available. 4. Interview with the laboratory liaison on 05/24/2022 at 12 pm confirmed the laboratory failed to document H&E stain quality assessment for five of five selected dates.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of patient test reports, record request, and interview with the laboratory liaison, the laboratory failed to document control slide reactions for special stains for five of five dates selected from 2021 and 2022. The findings include: 1. Observation of the laboratory on 05/24/2022 at 9 am revealed special stains in use for staining tissue for histopathology (Warthin Starry (silver), Alcian Blue and Periodic Acid Schiff). 2. Review of patient test records revealed the following for selected patient reports: TGJ21-0238-0000002--reported on 11/08/2021 with documented silver stain results TGJ21-0238-0000526--reported on 12/13/2021 with documented silver stain and alcian blue stain results TGJ22-0238-0000381--reported on 01/27/2022 with documented silver stain results TGJ22-0238-0001555--reported on 04/01/2022 with documented silver stain results TGJ22-0238-0002457--reported on 05/12/2022 with documented silver stain and alcian blue stain results 3. Request made to the laboratory liaison on 05/24/2022 at 11 am for stain quality control records revealed no records were available. 4. Interview on 05/24/2022 at 12 pm with the laboratory liaison confirmed there was no documentation of quality control/reactions for special stains for five of five selected patient cases/dates ranging from 11/08/2021 to 05/12/2022.