Commonwealth Diagnostics

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Code: **0176U** "Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)"

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Public Comment	Rationale
• CPT 86828 x 1 ($64.19) • i.e., recommendation to crosswalk 0176U to code for “Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens”	• Similar pre-analytic characteristics • Similar analytic methodology • Similar post-analytic steps

Test purpose, method, costs, and charges

- **<u>Test purpose</u>:**
  - IBS*chek* is an is an in vitro diagnostic test used to aid in the diagnosis of Irritable Bowel Syndrome with Diarrhea Predominant or Mixed Symptoms (IBS-D or IBS-M) via the semi-quantitative detection of two biomarkers, anti-CdtB and anti-vinculin IgG antibodies, in human EDTA plasma and capillary blood.
  - No existing test on CLFS combines these biomarkers for this intended use
- **<u>Test method</u>:**
  - ELISA

Recommendation:
Crosswalk 0176U to HLA Class I & II antibody testing

CLFS Crosswalk:

- **CPT 86828 x 1** "Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens"

Rationale:

Pre-analytic similarities	Analytic similarities	Post-analytic similarities
• Specimen type • Collection methods • Shipping conditions • Specimen processing	• Analytes • Methodology • Detection antibody • Controls	• Result type • Reporting (each analyte reported separately)