



Client Communication

Meridian/Otsuka Urea Breath Test Collection Device Shortage

Clinical Pathology Laboratories (CPL) is experiencing a national shortage of the Meridian/Otsuka Urea Breath Test (UBT) for *Helicobacter pylori* detection. Collection kits are on backorder and requests for resupply may not be possible for a short period of time. In addition, certain patient service centers (PSC's) may not have collection supplies. Testing will continue to be performed at CPL subject to UBT kit availability. CPL is validating an alternative UBT method and collection device, and expects to reestablish client and PSC supply very quickly. Further details will follow.

In the interim, please consider:

1. Contact your account executive for collection device availability and anticipated resupply with the current or new device.
2. Have patients call their local PSC prior to scheduling testing to assure that collection supplies are available on site.
3. Consider *H. pylori* Stool Antigen (HPSA) test as an alternative for the diagnosis of *H. pylori* infection. While the collection of HPSA requires submission of a stool sample and may be more challenging for some patients, published data shows excellent sensitivity and specificity.

Test	Sensitivity	Specificity
H PYLORI BREATH TEST	95.2% [95%CI: (93,97)]	89.7% [95%CI: (73,98)]
H PYLORI AG, STOOL	100% [95%CI: (89,99)]	96.1% [95%CI: (89,99)]

NOTE: CPL has found that >90% of patients co-collected with UBT and Stool Antigen testing have concordant results.

Affected Testing		Alternative Testing	
Test Code	Name	Test Code	Name
5591	H PYLORI BREATH TEST	4499	H PYLORI AG, STOOL
5653	H PYLORI (BREATH), PEDIATRIC		

Please contact your local Account Executive with any questions.

