Technical Bulletin

Update on Testing for Sexually Transmitted Infections

TO: Medical Staff and Clients

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SUBJECT: **Resolution of increased percentage of invalid Chlamydia and gonorrhea results**

When DLS transitioned to the fully automated Roche cobas 6800, we experienced an unexpected increase in invalid rate from ~ 1% to ~ 10% with swabs specimens; however **not** with urines.

As part of the troubleshooting process and upon manufacturer recommendations, the media in the cobas® PCR Swab Sample Kit media was tested and validated. Although performance improved slightly, this did not completely resolve the problem. Further investigation suggested that carbomers, a chemical commonly found in lubricants and feminine hygiene products, was causing interference. According to the manufacturer, products containing carbomers have been shown to generate false negative and invalid results.

We resolved invalids with a 1:5 dilution; however, there may be a small impact on sensitivity when few organisms are in the sample. Urine is a reliable alternative that is easy to collect if swab samples are persistently invalid.

Our system performed extremely well in a multicenter study (Van Der Pool, et al. 2019 JCM. 57:4). Urines were comparable to swabs, the latter having slightly higher sensitivity. However, invalids were excluded from data analysis, so their impact (which in our experience was about 9% of swabs) was not disclosed. We have determined that invalids usually can be resolved with dilution, which equalizes the sensitivity with urines. When a swab specimen needs to be diluted and repeated, it increases turn-around time by an average of 1 day.

A new specimen collection guide is available on technical bulletin: **New collection kit and test expansion for Chlamydia and gonorrhea**: https://dlslab.com/documents/bulletins/2023/tech-memo-gc-ct-testing-expansion-6-1-2023.pdf

Please refer any questions to Jason Pon, Manager - DLS Molecular Laboratories at 808-441-5469 or DLS Client Services at 589-5101.