Agenda Item Number: 10

Benchmark Activity 29.1:
The local health department shall develop and implement policies ensuring that state and federal requirements are followed regarding the rights of participants in local public health research programs and requiring that any requests to access health department clients have Institution Review Board approval obtained by the host research organization

Durham County Board of Health
Agenda Item Summary

Meeting Date: December 11, 2014

Agenda Item Subject: ELITech *T. vaginalis* study

Attachment (s): Protocol Summary

Staff or Board Member Reporting: Arlene C. Sena, MD, MPH

Purpose:
____ Action
_____ Information only
__X____ Information with possible action

Objectives:

To review a new research study to be conducted in the DCoDPH STD Clinic by UNC-CH research staff, titled "A prospective, multi-center study to demonstrate the clinical performance of artus® *T. vaginalis* QS-RGQ MDx Kit on detecting the presence of *Trichomonas vaginalis* in subjects using DNA samples obtained from clinical specimens."

Summary Information:

With an estimated 7.4 million new trichomoniasis cases occurring annually in the United States, *Trichomonas vaginalis* infection is the most common, curable, non-viral, sexually transmitted disease (STD). Effective diagnosis and treatment of *T. vaginalis* infections in women are necessary to prevent disease acquisition, transmission, and associated complications.

ELITechGroup Inc Molecular Diagnostics (EGI MDx), in conjunction with QIAGEN, is developing a *T. vaginalis* screening test, the artus *T. vaginalis* QS-RGQ MDx Kit. The aims of this study are to establish the clinical performance of the artus *T. vaginalis* QS-RGQ MDx Kit for the detection of *Trichomonas vaginalis* in vaginal swabs, endocervical swabs and urine as compared to a combined reference testing

of vaginal swabs by wet mount microscopy and the FDA-cleared Hologic|Gen-Probe APTIMA *T. vaginalis* assay.

Eligible women ≤ 18 years of age will be recruited prior to their STD evaluation by research personnel. Following written informed consent, study subjects will undergo routine evaluations and additional specimen collection for study purposes, including urine, two vaginal swabs, and a cervical swab.

Eligible clinic patients will receive compensation for participation in the study. Enrolled women may also benefit by receiving more sensitive tests for TV infections than methods currently provided at the health department.

The resources to be requested from DCoDPH include:

1) recruitment of potential study participants from the STD clinic
2) space for recruitment, enrollment, and follow-up

Recommended Action:

____ Approve

_____ Approve & forward to Board of Commissioners for action

_____ Approve & forward to_____

____ Accept as information

_____ Revise & schedule for future action

_____ Other (details):_____

Protocol Summary: A prospective, multi-center study to demonstrate the clinical performance of artus® *T. vaginalis* QS-RGQ MDx Kit on detecting the presence of *Trichomonas vaginalis* in subjects using DNA samples obtained from clinical specimens.

Study participation will include a single clinic visit. Eligible women will be recruited prior to their STD evaluation by research personnel. Following written informed consent, study subjects will undergo routine evaluations including a patient history with demographic information, symptom review and past history of STDs. For study purposes, the following specimens will be obtained:

- First-catch urine (20-30mL) for testing with the artus® *T. vaginalis* test under evaluation.
- A total of 3 vaginal swabs will be collected:
  the first swab will be used for wet mount microscopy as per clinic protocol; the second will be suspended in the transport buffer of the APTIMA vaginal swab specimen collection kit for APTIMA *T. vaginalis* testing; the third swab will be used with the artus® *T. vaginalis* test under evaluation.

- One cervical swab will be collected:
  Following collection of an endocervical swab to be suspended in transport buffer for routine APTIMA STI testing at DCoDPH; one study-specific endocervical swab will be used with the artus® *T. vaginalis* test under evaluation.

APTIMA specimens will be transported daily by courier to the UNC STD research laboratory. Research study specimens will be sent daily to the sponsor's designated laboratory at Duke University for artus® *T. vaginalis* testing.

Results from the FDA-approved APTIMA test for trichomoniasis will be reported promptly to the STD clinic. Management and treatment of study subjects identified with trichomoniasis will follow routine clinic protocols.