Brief Summary of the Microbiology Devices Panel Meeting – August 16, 2016

Introduction:

On August 16, 2016, the Panel met to discuss and make recommendations regarding the the appropriateness of clearing or approving of over the counter (OTC) diagnostic tests for the detection of pathogens causing infectious diseases, focusing on respiratory and sexually transmitted infections (STI). The committee evaluated the benefits and risks to individual patients and to public health associated with clearing or approving OTC diagnostic tests for influenza, *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) and group A streptococcus (GAS). The committee also made recommendations on clinical study design, analytical study design, and acceptable performance criteria applicable to respiratory and STI OTC diagnostic devices. There were two presentations by guest speakers from the Centers for Disease Control and Prevention, Dr. Gail Bolan, M.D., and Dr. Stephen Lindstrom, Ph.D. There were five speakers during the open public comment period, representing Cepheid, Molecular Testing Labs, Ellume, Concentrics Research, and Luminostics. The panel engaged in a very robust discussion.

Deliberations:

The panel deliberated whether the benefits outweighed the risks for OTC assays for influenza, GAS, and CT/NG. The panel unanimously agreed that for OTC CT/NG assays the benefits outweighed potential risks. There was near unanimous agreement that benefits outweighed risks for OTC GAS assays as well. The panel did not come to an agreement on whether the benefits outweigh the risks for influenza OTC assays. For these assays the panel expressed concern that the potential low positive predictive value outside of the active influenza season was a high risk and that risk was difficult to mitigate under the current FDA regulatory framework.

There was unanimous agreement by the panel that FDA evaluate and assess the performance of future OTC diagnostics for infectious diseases against nucleic acid amplification test (NAAT) comparators. There was also agreement that OTC performance should be similar to that seen with NAAT assays for influenza and CT/NG, although there was less agreement regarding GAS.

Discussion also focused on how the package insert and any educational materials that were included with any OTC infectious disease diagnostic should be designed. The panel suggested risk mitigation statements that should be included prominently in the package insert regarding follow-up care and appropriate interpretation of results, particularly for CT/NG. The panel also strongly supported comprehensive human factors engineering studies targeted at user comprehension of directions, appropriate performance of the test, and accurate interpretation of results. The committee stressed that included material should be clear, simple and presented at an accessible reading level in multiple languages. Graphics should also be employed

to assist users with following test directions and interpreting results. Including a F.A.Q. (frequently asked questions) section in the package insert was also suggested and supported by the panel experts. The panel also discussed other educational approaches that could be helpful, including web-based materials, video instruction, etc.

During the discussion on clinical studies the panel emphasized the need for manufacturers to recruit patients at non-traditional sites that are not typically used during clinical studies for laboratory tests. Sites should focus on recruiting the intended users of the test once it is on the market. FDA encouraged manufacturers to take advantage of the pre-submission process to develop appropriate clinical study protocols.

Lastly, the panel discussed linkage to care. They encouraged test manufacturers to consider methods to aid patients to link with healthcare providers. Manufacturers were also encouraged to work with other appropriate organizations that can provide users with health information and to take advantage of technologies such as websites and apps to assist patients in linking to care and treatment. The panel also discussed cooperation across sponsors in providing this informational material.

The five public speakers during the public comment period, each representing a possible manufacturer of OTC tests, supported potential clearance or approval of OTC test for pathogens causing infectious diseases. These speakers also stressed the willingness of manufacturers to work with technology and other partners during product development to address concerns expressed by the panel regarding education of test users, epidemiological tracing of results, maintaining confidentiality of results, and other issues.

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