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SECTION 7
Summary of Substantial Equivalence

The VIDAS Chlamydia Blocking (CHB) assay used as a supplemental test to verify positive and equivocal results from female endocervical and male urtheral specimens in the VIDAS Chlamydia (CHL) assay and is substantially equivalent to cell culture for the qualitative detection of Chlamydia antigen.

Major similarities include:

1. Both the VIDAS Chlamydia Blocking assay and cell culture detect the presence of viable chlamydial antigens in patient specimens.

Major differences include:

1. Standard cell culture only detects viable antigen in female and male swab specimens. The VIDAS Chlamydia Blocking assay detects both viable and nonviable antigen in female and male swab specimens.

2. The VIDAS Chlamydia Blocking assay is a fully automated enzyme-linked fluorescent immunoassay (ELFA) and requires only the addition of the blocking and reference reagents to the VIDAS Chlamydia strips. Standard cell culture methodologies are labor intensive and requires confirmation by Giemsa, iodine, or fluorescent antibody staining.

3. Along with the VIDAS Chlamydia assay results for the VIDAS Chalmydia Blocking assay can be obtained within 2 1/2 hours. Cell culture methodologies require at least 48 hours to obtain results.

The data comparing the performance of the VIDAS Chlamydia Blocking assay to that of cell culture can be found in Section 8 of this submittal.