

Draft Questions for Panel:

1. Does the data collected permit adequate assessment of this device as an aid in the detection of bacteria associated with urinary tract infection?
2. Results of the OMA-UT1 when compared to standard culture showed a high number of false positive results. Given confounding factors such as reduction in bacterial numbers due to antibiotic use or production of high levels of metabolites with some bacteria, are there any other comparative methods that may provide improved data results?
3. The detection threshold of the OMA-UT1 has been set to detect levels of volatile metabolites found in specimens with bacterial counts  $\geq 1 \times 10^5$  CFU/mL for either single colonies or mixed colonies containing at least one predominant organism  $\geq 1 \times 10^5$  CFU/mL. What labeling considerations should be given for bacterial counts below  $1 \times 10^5$  CFU/mL that may be clinically significant?
4. What warnings, limitations or precautions should be included in the labeling if this device is to be used as an indirect measure of urinary tract infection.