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SUMMARY: Safety and Effectiveness Information for the VIDAS Rotavirus Assay

The VIDAS Rotavirus (RTV) Assay detects the presence of rotavirus antigen in stool specimens. It is substantially equivalent to the Cambridge Biotech Rotaclone Rotavirus Diagnostic Kit. Safety and effectiveness issues for qualitative antigen detection enzyme immunoassays such as the VIDAS RTV Assay may include the following:

1. **False positive results:** In studies comparing the VIDAS RTV Assay to one commercially available EIA with resolution of discrepancies by a second EIA, there were 7 false positive samples. This results in a relative specificity of 95.1%, with overall agreement of 96.5%.
2. **False negative results:** In studies comparing the VIDAS RTV Assay to one commercially available EIA with resolution of discrepancies by a second EIA, there were 6 false negative samples. This results in a relative sensitivity of 96.4%, with overall agreement of 96.5%.
3. The 13 discrepant samples were further tested with EM. Of the 13 discrepant results, 4 resolved positive and 4 resolved negative in agreement with VIDAS RTV. Three specimens were VIDAS positive and EIA negative, confirmed negative. One specimen was VIDAS negative and EIA positive, confirmed positive. One discrepant result was not tested. The overall agreement of all samples is 94.8%
4. **Equivocal results:** In the studies done to support the VIDAS RTV Assay performance claims, there were 4 equivocal results when following package insert instructions.
5. **Invalid results:** In the studies done to support the VIDAS RTV Assay performance claims, there were no invalid results.
6. **Cross-reactivity and interference:** A panel of approximately 50 microorganisms representing normal enteric flora or common enteric pathogens was tested in the VIDAS RTV Assay. No cross-reactivity or interference was observed with the organisms tested.
7. **Precision:** In the studies done to support the VIDAS RTV Assay performance claims, the intra-assay precision testing showed coefficients of variation of less than 10%. The inter-assay precision testing gave coefficients of variation of less than 10%.
8. **Assay specificity is conferred by the use of two anti-rotavirus antibodies.** The rotavirus antigen is captured on the SPR by a polyclonal anti-rotavirus VP6 antibody, and the detector antibody conjugate is composed of a mouse monoclonal anti-rotavirus VP6 antibody.
9. **Limit of detection:** The limit of detection is defined as the concentration of organism yielding a test value greater than the negative threshold. The results of testing known concentrations of rotavirus antigen (quantitated via EM) in the VIDAS RTV Assay showed the limit of detection to be approximately 2.3×10^2 viral particles/ml.

The VIDAS RTV Assay must be used according to package insert instructions when testing stool specimens for the presence of rotavirus antigen. Additional information and references may be found in the package insert.