K971895

bioMérieux

OCT - 3 1997

J.1 510(k) Summary

Submitter: Terry McGovern
bioMérieux Vitek, Inc.
1022 Hingham St.
Rockland, MA 02370
(617) 871-4442

Date: August 1, 1997

Device: VIDAS Rotavirus (RTV) Assay

Classification Name: Enzyme Linked Immunoabsorbent Assay, Rotavirus (83LIQ)

Predicate Device: Cambridge Biotech Rotaclone Assay

Intended Use: The VIDAS Rotavirus (RTV) Assay is for the qualitative detection of rotavirus antigen in stool specimens. It is intended as an aid in the diagnosis of acute nonbacterial gastroenteritis.

Device Description:

The VIDAS Rotavirus (RTV) Assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated VIDAS (Vitek ImmunoDiagnositic Assay System) instrument. All assay steps and the assay temperature are controlled by the instrument.

The VIDAS Rotavirus Assay contains a pipette tip-like disposable device, the Solid Phase Receptacle (SPR), a Reagent Strip, 1 Bottle of Standard, 1 Bottle of Positive Control, and 1 Bottle of Negative Control. The Kit contains a sufficient number of SPR's and Strips to perform 60 Tests.

The SPR serves as the solid phase, as well as, the pipettor for the assay. The SPR is coated with rabbit anti-rotavirus antibodies. The Strip contains the reagents necessary to perform the assay, as well as, a sample well for placement of the specimen. Each RTV Assay requires one RTV Reagent Strip and one RTV SPR.

Synopsis of Test Methods and Results

bioMérieux Vitek, Inc. has determined that the proposed change in labeling claims will not impact the safety and effectiveness of the VIDAS Rotavirus Assay. Below please find a synopsis of test methods used to verify this:

1. False Positive Results: In studies comparing the VIDAS RTV Assay to one commercially available EIA there were 8 false positive samples. This results in a relative specificity of 95.8% with overall agreement of 94.6%. Comparing the VIDAS RTV to a second EIA resulted in 8 false positives. This results in a relative specificity of 95.7% with an overall agreement of 92.4% In a study comparing VIDAS RTV Assay to Electron Microscopy, there were no false positive samples.

2. False Negative Results: In studies comparing the VIDAS RTV Assay to one commercially available EIA there were 9 false negative samples. This results in a sensitivity of 92.7% with overall agreement of 94.6%. Comparing the VIDAS RTV to a second EIA resulted in 16 false negative samples. This results in a relative sensitivity of 87.8% with an overall agreement of 92.4%. In a study comparing the VIDAS RTV Assay to Electron Microscopy, there were 3 false negative results this results in a sensitivity of 95.7% with overall agreement of 97.0%.

3. Thirteen discrepant samples from the VIDAS vs. EIA studies 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 5 equivocal results when following the 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 of 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 3.16×10^2 VP/mL in formed stool; 6.28×10^2 VP/mL in semisolid stool; and 1.44×10^5 VP/mL in liquid stool.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Terry McGovern
Manager, Quality Assurance/Regulatory Affairs
bioMerieux Vitek, Inc.
1022 Hingham Street
Rockland, MA 02370

Re: K972895
Trade Name: VIDAS Rotavirus (RTV) Assay
Regulatory Class: I
Product Code: LIQ
Dated: August 1, 1997
Received: August 5, 1997

Dear Ms. McGovern:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in-vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: VIDAS Rotavirus Assay

Indications for Use:

The VIDAS Rotavirus (RTV) assay is for the qualitative detection of rotavirus antigen in stool specimens. It is intended as an aid in the diagnosis of acute nonbacterial gastroenteritis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972895

Prescription Use X or Over-the-Counter Use_____