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Section: Serology Manual	Subject Title: Varicella-Zoster Virus IgG VIDAS System	
Issued by: LABORATORY MANAGER	Original Date: March 14, 2001	
Approved by: Laboratory Director	Revision Date: May 27, 2003	

VARICELLA-ZOSTER VIRUS IgG

I. Introduction

Varicella-Zoster IgG assays is used for evaluating patient's immune status to Varicella-Zoster viruses infection. The VIDAS is an enzyme-linked fluorescent immunoassay (ELFA) utilizing a virus coated Solid-Phase-Receptacle (SPR) to which antibody in serum binds. Anti-Human IgG conjugated with Alkaline Phosphatase reacts with substrate, 4-Methylumbelliferyl Phosphate to form a fluorescent product. All necessary reagents and test serum are contained in the VZG reagent strips.

II. Specimen Collection and Processing

Blood (5 mL) is collected in a serum separator tube and separated by centrifugation. The serum is removed to a vial and refrigerated until testing. Specimens are stored at -20°C after testing.

III. Procedure

Reagents

VIDAS Varicella-Zoster IgG test kit:
VZG Reagent Strips
VZG SPRs
Standard
Positive Control
Negative Control

Other materials:
Pipettor 100 uL

Method

1. Bring test kit and serum samples to room temperature. Check that lot number of kit matches lot currently in use (as posted on VIDAS instrument). If lot number does not match, ensure that all kits/test strips for the posted lot number have been used.

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Enter new lot data by inserting bar code card found in kit into instrument using "7. Calibration Menu", "2. Read Master Lot Entry Card from Instrument", "Enter section to read data from (enter section letter)".

Post card of new lot currently in use on VIDAS along with the date.

2. Label MSG/VZG strips as follows:
 - s (Standard)
 - s (Standard)
 - C1 (Positive Control)
 - C2 (Negative Control)
 - 5
 - 6 etc. up to 30

3. Pipette 100 uL of Standard, Control or serum into the specimen well of the corresponding VZG strips. Check for adequate sample level and remove any bubbles.

4. At VIDAS instrument, start at Main Menu.
 - a) **Enter 1) "Create a Work List", "ENTER".**
 - b) **"Do you want to reserve sections now (y)?" "ENTER"**
 - c) **"Enter technologist name" (enter initials here)**
 - d) **"Enter assay code" (enter VZG here).**
 - e) **"Enter number of VZG tests" (enter number here).**
Include standards and controls.
 - f) **"Enter sample ID":**
Enter s (two positions automatically used)
C1
C2
5
6 etc.
 - g) When finished, hit **"ENTER"**

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- h) Recheck worklist entries.
 Hit **"ENTER"** to accept worklist,
 "d" to delete any entries,
 OR
 "m" to modify any entries.
- i) **"Do you want a worklist fill report"**,
 hit **"n, ENTER"**.
- j) Load VZG strips according to assigned module
 positions on the worklist.
- k) Load one VZG SPR for each VZG strip.
- l) **"Run worklist now"**, hit **"y, ENTER"**.
- m) Assay is complete when results are printed
 and module lights are blinking.
- n) If instrument is beeping, exit program (11) to the vid prompt. Type
 "message". To re-enter to the main menu type "vid", enter.
- o) If computer is not responding, log in: vid, password: enter (blank).

Interpretation of Results

Specimens with test values greater than 0.9 (MEA/VZ) are considered positive. Test values ranging from 0.6-0.9 are equivocal.

Samples with test values less than 0.6 (MEA/VZ) are considered negative.

IV. Reporting

Positive: Varicella-Zoster antibody: Positive

Equivocal: Varicella-Zoster antibody: Equivocal

Negative: Varicella-Zoster antibody: Negative

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V. Quality Control

Standard: RFV must be greater than or equal to RFV range posted on VIDAS instrument.

Positive and Negative Control: Test Values must be within ranges posted on VIDAS.

Quality Control ranges posted on VIDAS may change from lot to lot, therefore it is essential that the lot number of the test kit in use corresponds to that of the posted values.

Refer to a senior technologist if control results are outside of limits or for any other problems with running or reporting the assay.

Run external control (pooled positive sera) with each new lot. Results filed in Reagent Lot Binder. If result is negative, the run is invalid. Inform Charge/senior technologist, and repeat testing.

CAP provides external proficiency testing.

VI. Reference

Manufacturer's Package Insert.
VIDAS System Operational Manual.
bioMerieux-Vitek, Inc.
Missouri, USA 64042-2395