REF **01-470** 96-Test Set IVD

For in Vitro Diagnostic Use Only

Intended Use: For the qualitative and semi-quantitative detection of human IgG antibodies to Epstein-Barr (EB) viral capsid antigen (VCA) in human serum by enzyme immunoassay. The test may be used in conjunction with other serologicals, as an aid in the diagnosis of infectious mononucleosis.

Summary of Test

1. **Prepare 1:51 dilutions of Calibrator(s), Controls and samples. Mix well.**
2. **Place 100 µl of the dilutions in the Coated Wells; reserve one well for the reagent blank.**
3. **Incubate at room temperature for 30 ± 5 minutes.**
4. **Drain wells thoroughly. Wash wells 4 times with Wash Solution and drain.**
5. **Place 2 drops (or 100 µl) of Conjugate in wells.**
6. **Incubate at room temperature for 30 ± 5 minutes.**
7. **Drain wells thoroughly. Wash wells 4 times with Wash Solution and drain.**
8. **Place 2 drops (or 100 µl) of Substrate in wells.**
9. **Incubate at room temperature for 30 ± 5 minutes.**
10. **Stop the enzyme reaction with 2 drops (or 100 µl) of Stop Reagent.**
11. **Read absorbance at 405 nm against reagent blank.**

Summary and Explanation of Test

Epstein-Barr virus (EBV) is the etiological agent of infectious mononucleosis (IM) (1). The designation of infectious mononucleosis classically refers to an Epstein-Barr virus-induced illness in young adults characterized by reactive blood smears, exudative pharyngitis, prominent cervical lymphadenopathy and serologically detectable heterophil antibodies. These clinical manifestations can also be caused by a number of other pathogenic agents including cytomegalovirus, Toxoplasma gondii, rubella virus, hepatitis virus, human immunodeficiency virus (HIV), and uncommonly by drugs such as Halothane, Hydantoin, Dapasone and Azulfidine (2, 3, 4).

Diagnosis of acute EBV IM is generally confirmed by a positive heterophil antibody test. The severity of the disease however, is not indicated by the relative titer of heterophil antibodies (5). In addition, difficulties in diagnosis arise when the heterophil antibody test is negative, or when the clinical manifestations are atypical or unusually severe.

Heterophil-negative IM occurs in 10 to 20 percent of adults, and in an even greater percentage of children (6, 7). IM diagnosis in these individuals may be confirmed by the detection and identification of antibodies to specific EB antigens which include: viral capsid antigen (VCA), early antigens, diffuse and restricted (EA-D and EA-R), and Epstein-Barr nuclear antigen (EBNA).

IgG antibodies to VCA may be present early during EBV infection, but they persist indefinitely after the occurrence of clinical disease, and may merely indicate EBV infection at some time in the past. IgM antibodies to VCA on the other hand, are present in the circulation 1 to 6 weeks after the onset of EBV illness and usually disappear in 3 to 6 months. Thus the presence of VCA IgM usually suffices for the diagnosis of acute IM. Further verification may be obtained by testing for the presence of antibodies directed against the other EBV-specific antigens, early antigen and EBNA. Heterophil antibody negative sera demonstrating VCA IgM and transient levels of antibody to early antigen are considered diagnostic for acute IM. In contrast, antibodies to EBNA appear late during IM infections, and IgG antibodies to EBNA may persist for years, even for life, and are indicative of the convalescent phase of IM infection.

The EB VCA IgG EIA test is an ELISA test which utilizes a microwell format. Test results are obtained after one and one-half hours incubation time. They are objective and normalized as Index values, permitting uniformity of reporting.

Principle of the Test

Diluted samples are incubated in VCA antigen-coated wells. VCA IgG antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme labeled antibodies to human IgG) is added and incubated. If IgG antibodies to VCA are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end product which is read photometrically.

Reagents

Coated Wells	Coated with inactivated Epstein-Barr VCA antigen 12 eight-well strips.
Well Support	One.
Diluent*	25 mL (pink color). Phosphate-buffered saline with a protein stabilizer.
Calibrator 1*	0.3 mL. Human serum. Strongly reactive for VCA IgG antibodies.
Calibrator 2*	0.3 mL. Human serum. Moderately reactive for VCA IgG antibodies.
Positive Control*	0.3 mL. Human serum. Reactive for VCA IgG antibodies.
Negative Control*	0.3 mL. Human serum. Non-reactive for VCA IgG antibodies.
Conjugate	12 mL (green color). Goat anti-human IgG labeled with alkaline phosphatase (calf).
Substrate	12 mL. p-nitrophenyl phosphate.

Note: The substrate may develop a slight yellow color during storage. One hundred microliters of substrate should yield an absorbance value less than 0.35, when read in a microwell against air or water.

Wash Concentrate* 30 mL. Tris-buffered saline with Tween 20, pH 8.0. Prepare Wash Solution by adding the contents of the Wash Concentrate bottle to liter of distilled or deionized water.

Stop Reagent 12 mL. Trisodium Phosphate 0.5 M.

* Contains 0.1% sodium azide.

Store these reagents according to the instructions on the bottle labels. Do not allow them to contact the skin or eyes. If contact occurs, wash with copious amounts of water.

Other Materials Required

1. Microplate washer
2. Pipettors for dispensing 8, 100 and 200 µl

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3. Timer
4. 1 or 2 liter container for Wash Solution
5. Distilled or deionized water
6. Dilution tubes or microwells
7. Microwell reader capable of reading absorbance at 405 nm. Dual wavelength readers are recommended.

Precautions

1. For in vitro diagnostic use.
2. Test samples, Calibrator(s), Controls and the materials that contact them, should be handled as potential biohazards. The calibrators and controls have been found to be negative for HIV, hepatitis B surface antigen and HCV antibodies by FDA licensed tests. However, because no method can offer complete assurance that HIV, hepatitis B virus, HCV or other infectious agents are absent, these materials should be handled at the Biosafety Level 2 as recommended for any potentially infectious serum or blood specimen in the Centers for Disease Control/National Institutes of Health Manual "Biosafety in Microbiological and Biomedical Laboratories", 1993, or latest edition.
3. The concentrations of anti-EB VCA IgG in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity.
4. Avoid contact with open skin.
5. Never pipet by mouth.
6. Certain of the test reagents contain sodium azide. Azides are reported to react with lead and copper in plumbing to form compounds that may detonate on percussion. When disposing of solutions containing sodium azide, flush drains with large volumes of water to minimize the build-up of metal-azide compounds. For further information, refer to product MSDS.
7. Do not interchange reagents from different reagent lots, except for Wash Concentrate, Substrate and Stop Reagent.
8. Do not use reagents beyond their stated expiration date.
9. Incubation times recommended in the Test Procedure section should be adhered to.
10. Unused Coated Wells should be kept in their resealable bag with dessicant, and stored in the refrigerator.

Specimen Collection

Sera should be separated from clotted blood. If specimens are not tested within 8 hours, they should be stored at 2 to 8° C. for up to 48 hours. Beyond 48 hours specimens should be stored at -20° C. or below. Multiple freeze-thaw cycles should be avoided. Samples containing visible particulate matter should be clarified by centrifugation; and hemolyzed, icteric or grossly contaminated samples should not be used. Samples should not be heat-inactivated before testing.

Test Procedure

Allow all reagents and patient samples to reach room temperature before use. Return them promptly to refrigerator after use.
1. Prepare 1:51 dilutions of test samples, Calibrator(s), Positive and Negative Controls, in the test set Diluent. For example: add 4 µl of sample to 200 µl of Diluent in a dilution well or tube, and mix well.

Note: A single Calibrator (Calibrator 2) may be used; or Calibrator 1 and Calibrator 2 may be used to prepare a calibration curve.

2. Place an appropriate number of Coated Wells in the Well Support.

Note: For combination testing (multiple assays per plate), the strips should be assembled on a white background with good lighting. Be sure to note the placement of each strip and the corresponding color.

3. Transfer 100 µl of each diluted Calibrator, Control and patient sample to the wells.

Note: Include one well which contains 100 µl of Diluent only. This will serve as the reagent blank and will be ultimately used to zero the photometer before reading the test results, or it may be used as the zero point in a calibration curve.

4. Incubate the wells at room temperature (20 to 25° C.) for 30 ± 5 minutes.
5. Wash wells four times with at least 250 µL/well/wash. Do not allow the wells to soak between washes. Drain thoroughly after the last wash.
6. Place 2 drops (or 100 µl) of Conjugate into each well.
7. Incubate the wells at room temperature for 30 ± 5 minutes.
8. Wash wells four times with at least 250 µL/well/wash. Do not allow the wells to soak between washes. Drain thoroughly after the last wash.
9. Place 2 drops (or 100 µl) of Substrate into each well.
10. Incubate at room temperature for 30 ± 5 minutes.
11. Place 2 drops (or 100 µl) of Stop Reagent into each well.
12. Read and record the absorbance of the contents of each well at 405 nm against the reagent blank.

Note: Adjust the photometer to zero absorbance at 405 nm against the reagent blank. Readings should be made within 2 hours after the reactions have been stopped.

Calculation of Results

Test results may be calculated using a single calibrator (Calibrator 2), or using a calibration curve.

Single Calibrator (Calibrator 2)

Determine the Index value for each test sample (or Control) using the following formula:

$$\frac{\text{Calibrator Index}}{\text{Calibrator Absorbance}} \times \text{Test Sample Absorbance} = \text{Test Sample Index}$$

If the Calibrator is run in duplicate, use the average absorbance value to calculate results.

Calibration Curve

Alternatively, test results may be calculated from a three-point curve comprised of: Calibrator 1 (high-point), Calibrator 2 (mid-point) and the reagent blank (zero / origin), using a point-to-point curve fit.

Quality Control

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1. The Calibrator(s), Positive and Negative Controls must be included in each test run.
2. The absorbance value of Calibrator 1 must be at least 0.4 when read against the reagent blank.
3. The absorbance value of the reagent blank should be less than 0.35.
4. The Negative Control must have an Index value less than 0.9.
5. The Positive Control must have an Index value equal to, or greater than 1.1, when using a single Calibrator (Calibrator 2). When using the calibration curve, the Positive control must have an Index value within the range printed on the label. Users may supply an alternative Positive Control if they wish.
6. The Negative and Positive Controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cutoff. Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations. For guidance on appropriate quality control practices, please refer to NCCLS document C24-A, *Internal Quality Control Testing: Principles and Definitions.*

Interpretation of Results

Index Value	Interpretation
< 0.9	Negative for anti-EB VCA IgG antibody
≥ 1.1	Positive for anti-EB VCA IgG antibody
≥ 0.9 < 1.1	Equivocal*

*Index values which fall between 0.9 and 1.1 indicate an equivocal result. Subsequent samples should be drawn at least fourteen days later and tested simultaneously with the initial sample. If the subsequent sample is positive, seroconversion has occurred, which may be indicative of recent infection. If the subsequent sample remains equivocal, antibody status is undetermined and the sample is deemed equivocal. Other clinical and serological evidence should be sought in these cases.

The EB VCA IgG EIA cut-off values were based on statistical analyses, of the results of tests of 25 serum specimens which were negative for anti-VCA IgG antibodies when tested by another commercial VCA IgG test. The cutoff values were challenged in tests of positive and negative specimens (see Performance Characteristics).

Specimens which yield absorbance values above the range of the test set calibrator(s), may be pre-diluted in the test set Diluent and reassayed. The resulting Index value must be multiplied by the dilution factor. Example: If the specimen has been pre-diluted 1:5 before testing, the resulting Index value should be multiplied by 5.

Semi-quantitative Interpretation:

Dose response experiments have been performed at Laboratory B (Miami, FL) by assaying serial dilutions of positive specimens. Typical results of these experiments are shown in Figure 1. An analysis of these experiments was performed to establish the criteria for recognizing significant changes in antibody levels. To determine significant differences between EB VCA IgG EIA Index values, calculate the ratio of the Index values, by dividing the larger Index value by the smaller one. If the ratio is ≤ 2.00, the difference is not significant. If the ratio is between 2.01 and 3.87, the difference is equivocal. If the ratio is ≥ 3.88, the difference is significant.

Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgG level cannot be correlated to an endpoint titer. The magnitude of the assay result above the cut-off is not an indicator of the total antibody present.

Specimens collected too early during the course of the disease may not contain anti-EB VCA IgG antibody.

Limitations

The results obtained with the EB VCA IgG EIA test serve only as an aid to diagnosis and should not be interpreted as diagnostic in themselves. Test results should be evaluated in relation to patient symptoms, clinical history, and other laboratory findings.

The timing of the appearance of IgG antibodies to VCA is subject to variations among individuals and serological assays.

Some sera drawn very early at the onset of symptoms, may not contain detectable levels of VCA antibody and may require the drawing of another test specimen 1-2 weeks later.

The assay's performance characteristics with immunosuppressed individuals have not been established.

The prevalence of IgG antibodies to VCA will affect the assay's predictive value.

This assay is not intended for viral isolation and/or identification.

The assays performance characteristics have not been established for testing newborn specimens, or cord blood, or matrices other than human serum.

Dose response experiments have demonstrated that specimens yielding EB VCA IgG EIA Index values up to 89.2 do not exhibit a high-dose hook effect.

The assays performance characteristics were not established for visual result determination.

Expected Values

Nearly all individuals have been infected with EBV by the time they reach adulthood (8). Characteristically, IgG antibodies to VCA appear relatively early during IM infections and persist for years, even for life.

Serum samples obtained randomly from 57 normal South Florida blood donors were assayed by the EB VCA IgG EIA test. All 57 samples tested positive for IgG antibodies to VCA. The samples yielded index values between 1.1 and 20.8, with a mean index value of 13.8.

Table 1. Results of EB VCA IgG EIA Tests of 57 Archival Specimens (frozen), from Normal South Florida Blood Donors. The Assays were Performed at Laboratory B (Miami, FL).

Index Value Ranges	Specimens	
< 1.1	0	0 %
≥ 1.1 to < 5	6	10.5 %
≥ 5 to < 15	20	35.1 %
≥ 15	31	54.4 %

Performance Characteristics

Comparative Testing

The results of EB VCA IgG EIA tests correlate well with other commercial serological tests. Serum specimens obtained from normal South Florida blood donors, from patients whose sera were submitted to clinical laboratories in South Florida for diagnostic testing, and from serum brokers, were assayed by the EB VCA IgG EIA test, and other commercial serological assays. The assays were performed at an independent laboratory (Lab A, Miami, FL), and at Laboratory B (Miami, FL). Forty-eight percent of the serum specimens tested at Laboratory A were from female donors ranging in

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age from 1 to 89 years (mean = 24 years). Fifty-two percent were from male donors between 1 and 75 years of age (mean = 28 years). The results obtained in these studies are shown below in tables 2 and 3, respectively.

Table 2. Results of Tests of 90 Archival Patient Specimens Tested at Laboratory A (Miami, FL) Using the EB VCA IgG EIA Test and Another Commercial Test

	Comparative EB VCA IgG EIA					
Test #1	Positive	Equivocal	Negative		%	95%CI**
Positive	74	2	0	Relative sensitivity*	100	96.0 to 100
Equivocal	0	0	0			
Negative	7	4	3	Relative specificity*	30	1.6 to 58.4
* Excluding equivocal results				Overall Agreement*	91.7	85.8 to 97.6

** Calculated by the Normal Method (7).

Table 3. Results of Tests of 157 Archival Patient Specimens Tested at Laboratory B (Miami, FL) Using the EB VCA IgG EIA Test and Another Commercial Test.

Comparative	EB VCA IgG EIA					
Test #2	Positive	Equivocal	Negative		%	95%CI**
Positive	130	2	11	Relative sensitivity*	92.2	87.8 to 96.6
Equivocal	2	1	0			
Negative	1	1	9	Relative specificity*	90.0	71.4 to 100
* Excluding equivocal results				Overall Agreement*	92.1	87.7 to 96.4

** Calculated by the Normal Method (7).

Please be advised that "relative" refers to the comparison of this assay's results to that of a similar assay. There was not an attempt to correlate the assay's results to disease presence or absence. No judgement can be made on the comparison assay's accuracy to predict disease.

Sensitivity and specificity relative to serological profile

One hundred and fifty-seven archival serum specimens (see table 3) were tested at Laboratory B using the EB VCA IgG EIA test, and other commercially available EIA tests for detecting VCA IgG, VCA IgM and EBNA IgG. One hundred and thirty-seven of these sera were able to be characterized as acute (VCA IgM antibody present and EBNA IgG antibody absent), seropositive (VCA IgG and EBNA IgG antibodies present and VCA IgM antibodies absent) or seronegative (no serological evidence of EBV IgM, EBV IgG or EBNA IgG antibodies), on the basis of their serological profile. The sensitivity, specificity and agreement of the EB VCA IgG EIA assay were determined based on these characterizations. It was assumed that the VCA IgG response should be negative for seronegative samples, and positive for the acute and convalescent samples. The results have been summarized below in table 4.

Table 4. Results of Tests Performed at Laboratory B, with 137 Selected Serum Specimens, Using the EB VCA IgG EIA Test, and Other Commercially Available Tests for VCA IgG, VCA IgM and EBNA IgG Antibodies.

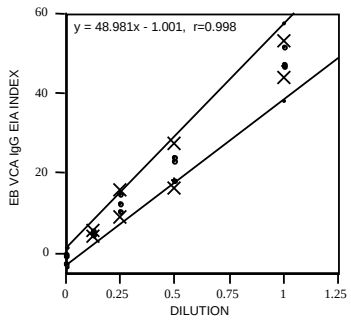
	Serum Characterization		
	Acute VCA IgM + EBNA IgG -	Seropositive VCA IgM - VCA IgG + EBNA IgG +	Seronegative VCA IgM - VCA IgG - EBNA IgG -
EB VCA IgG EIA			
Positive	21	100	0
Negative	3	2	9
Equivocal	1	0	1
Total	25	102	10

Relative sensitivity (Acute) = 21/24 = 87.5 %, 95 % CI = 74.3 % to 100 %
Relative sensitivity (Seropositive) = 100/102 = 98.0 %, 95 % CI = 95.3 % to 100 %
Relative specificity (Seronegative) = 9/9 = 100 %, 95 % CI = 92.0 % to 100 %
Relative agreement = 130/135 = 96.3 %, 95 % CI = 93.1 % to 99.5 %
Equivocal results were not included in the calculations, nor were they retested.
95 % confidence intervals (CI) were calculated using the normal method.
The seronegative 95% confidence interval was calculated assuming 0.1 false positive.

Titration Curve

Several strongly positive serum specimens were serially diluted (two-fold) in triplicate in the test kit Diluent, and assayed by the EB VCA IgG EIA test. Typical results are shown in Figure 1.

Figure 1. Titration Curve for a Strongly Positive Specimen.



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The triplicate data for each dilution are shown as points, the 95% confidence limits for each set of triplicate data are indicated by (x's), and the 95% confidence limits for the slopes and y-intercepts are represented by straight lines. The formula for the linear regression for the triplicate data is also shown in Figure 1.

Cross-reactivity study

The EB VCA IgG EIA test does not cross-react with antibodies directed against other Epstein-Barr virus antigens, other herpes viruses, and other unrelated viruses. Of ten specimens which were unreactive in the EB VCA IgG EIA test, 2 were positive for VCA IgM antibody, 3 EB NA antibody, 2 herpes simplex virus antibody, 3 cytomegalovirus antibody, 3 varicella zoster virus antibody, 4 rubella antibody and 2 measles antibody.

Precision

Eight serum specimens (2 negative and 6 positive) and the EB VCA IgG EIA Positive and Negative Controls, were assayed in triplicate, on three separate occasions.

The precision experiments were performed manually at an independent laboratory (Lab A), and at Laboratory B. These results are shown below in tables 5 and 6, respectively.

Table 5. Results Intra-assay and Interassay Precision Tests Performed at Lab A. Values were calculated from EB VCA IgG EIA Index Values.

	INTRA-ASSAY			INTERASSAY		
SAMPLE	MEAN INDEX	S.D	C.V. %	MEAN INDEX	S.D	C.V. %
Pos. Control	2.6	0.115	2.6	4.2	0.316	7.6
Neg. Control	0.8	0.058	NA	0.8	0.000	NA
1	0.3	0.000	NA	0.3	0.067	NA
2	0.3	0.058	NA	0.3	0.000	NA
3	7.1	0.874	12.2	6.8	0.719	10.6
4	5.4	0.115	2.2	5.4	0.497	9.2
5	3.0	0.115	3.9	2.9	0.141	4.9
6	3.6	0.306	8.4	3.6	0.265	7.4
7	4.2	0.350	8.3	4.3	0.330	7.8
8	4.0	0.250	6.3	3.7	0.360	9.8

Table 6. Results Intra-assay and Interassay Precision Tests Performed at Lab B. Values were calculated from EB VCA IgG EIA Index Values.

	INTRA-ASSAY			INTERASSAY		
SAMPLE	MEAN INDEX	S.D	C.V. %	MEAN INDEX	S.D	C.V. %
Pos. Control	9.1	0.231	9.1	2.4	0.207	8.5
Neg. Control	0.3	0.058	NA	0.2	0.000	NA
1	0.3	0.000	NA	0.3	0.053	NA
2	0.2	0.000	NA	0.2	0.033	NA
3	6.7	0.321	4.8	6.4	0.381	6.0
4	6.9	0.400	5.8	6.5	0.451	6.9
5	3.3	0.577	17.3	2.9	0.468	16.3
6	4.4	0.361	8.2	4.0	0.438	10.9
7	6.6	0.400	6.2	5.8	0.620	10.7
8	4.4	0.100	2.3	4.1	0.490	12.0

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Manufacturer:
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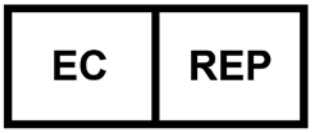

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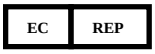
Symbols Glossary

Symbol	Standard Title and Number	Title of Symbol	Symbol reference #	Explanatory Text
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Authorized representative in the European Community	5.1.2	Indicates the Authorized representative in the European Community.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Use-by-date	5.1.4	Indicates the date after which the medical device is not to be used.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Catalog number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Temperature limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Consult instruction for use	5.4.3	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	*In vitro* diagnostic medical device	5.5.1	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Contains sufficient for 96 tests	5.5.5	Indicates the total number of IVD tests that can be performed with the IVD kit reagents.
Rx Only	Guidance for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements	Rx Only	N/A	Caution: Federal law prohibits dispensing without prescription.

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