REF **01-480** 96-Test Set IVD

For in Vitro Diagnostic Use Only

Intended Use: For the qualitative detection of human IgM antibodies to Epstein-Barr (EB) viral capsid antigen (VCA) in human serum by enzyme immunoassay, as an aid in differentiating active or recent Epstein-Barr virus infection from past infection.

Summary of Test

1. **Prepare 1:26 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

This summary does not intend to imply additional performance claims other than those already indicated in the Intended Use section.

Epstein-Barr virus (EBV) is the etiological agent of infectious mononucleosis (IM), and has also been implicated in Burkitt's lymphoma and nasopharyngeal carcinoma (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 IgM 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. *Absorbents have been included in the Diluent to neutralize the affects of rheumatoid factor and IgG antibody*. VCA IgM antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme labeled antibodies to human IgM) is added and incubated. If IgM 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 Epstein-Barr virus gp125 antigen. 12 eight-well strips.
Well Support	One.
Diluent*	25 mL (pink color). Phosphate-buffered saline with a protein stabilizer and absorbents for neutralizing rheumatoid factor and IgG antibody.
Calibrator*	0.3 mL. Human serum. Moderately reactive for VCA IgM antibodies. Index value stated on vial label.
Positive Control*	0.3 mL. Human serum. Reactive for VCA IgM antibodies. Index value range stated on vial label.
Negative Control*	0.3 mL. Human serum. Nonreactive for VCA IgM antibodies. Index value range stated on vial label.
Conjugate	12 mL (green color). Goat anti-human IgM 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 1 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.

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Other Materials Required

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

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 IgM 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. More than one freeze-thaw cycle 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 1:26 dilutions of test samples, Calibrator, Positive and Negative Controls, in the test set Diluent. For example: add 8 µl of sample to 200 µl of Diluent in a dilution well or tube, and mix well.
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 the diluted Calibrator, Controls and patient samples 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.

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

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.

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Quality Control

1. The Calibrator, Positive and Negative Controls must be included in each test run.
2. The absorbance value of the reagent blank should be less than 0.35.
3. The Negative Control must have an Index value less than 0.9.
4. The Positive Control must have an Index value equal to, or greater than 1.1. Users may supply an alternative Positive Control which yields index values close to the assay cutoff, to challenge the assay at its critical level, if they wish.
5. The Negative and Positive Controls have been prepared from different lots of materials than the Calibrator, and 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.*

If any of these criteria are not met, the test is invalid and should be repeated.

Interpretation of Results

Index Value	Interpretation
< 0.9	Negative for anti-EB VCA IgM antibody
≥ 1.1	Positive for anti-EB VCA IgM 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.

Negative results do not rule out the diagnosis of disease associated with Epstein-Barr virus. The specimen may be drawn before appearance of detectable antibodies. Negative results in suspected early disease should be repeated in 3-4 weeks. This information should accompany the reporting of results to the clinician.

The EB VCA IgM EIA cutoff values were based on statistical analyses, of the results of tests of 126 serum specimens which were negative for anti-VCA IgM antibodies when tested by another commercial VCA IgM test.

The presence of IgM antibody to EB VCA suggests recent or current infection. Specimens which yield absorbance values above the range of the test set Calibrator, 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.

Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgM 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.

Limitations

The results obtained with the EB VCA IgM 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 IgM antibodies to VCA is subject to variations among individuals and serological assays.

Anti-VCA specific IgG may compete with IgM for binding sites, leading to false negative results. Rheumatoid factor, in the presence of specific IgG, may contribute to false positive results. The absorbent in the EB VCA IgM EIA Diluent is intended to neutralize the effects of rheumatoid factor and specific IgG. Studies have indicated that the absorbent was able to neutralize up to 98 % of the activity in a sample known to contain 3,328 IU/mL of rheumatoid factor activity.

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

The prevalence of the analyte will affect the assay's predicative value.

Testing should not be performed as a screening procedure on the general population. The predicative value of a positive or negative serologic result depends on the pretest likelihood of Epstein-Barr associated disease being present. Testing should only be done when clinical evidence suggests the diagnosis of this syndrome.

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

The assays performance characteristics have not been established for matrices other than serum.

The assays performance characteristics have not been established for testing newborn specimens, or cord blood.

Performance has not been adequately established in a pediatric population.

Performance characteristics have not been established for immunosuppressed individuals.

The assays performance characteristics have not been 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.

IgM antibodies to VCA rise during the acute phase of EBV infection, and decline to undetectable levels between the first week and twelfth week after onset of symptoms. According to a large epidemiological study, the highest incidence of symptomatic IM occurs in adolescents, 15-24 years, and varies due to seasonal, ethnic and geographical factors.

Serum samples obtained randomly from fifty normal South Florida blood donors were assayed by the EB VCA IgM EIA test. Forty- nine samples (98%) were negative for IgM antibodies to VCA. One sample was equivocal, having an Index value of 0.9. This sample was negative when tested by another microwell ELISA method. The mean Index value obtained for the fifty normal donors was 0.1.

Performance Characteristics

Comparative Testing

The results of EB VCA IgM 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 a South Florida clinical laboratory for EBV serology, and from serum brokers, were assayed by the EB VCA IgM 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). Twenty-seven (39.7%) of the serum specimens tested at Laboratory A were from female donors, ranging in age from 1 to 54

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years (mean = 25 years). Thirty-eight (55.8%) were from male donors ranging in age from less than 1 year to 91 years (mean = 35 years). Three (4.5%) of the donors were nor identified. The test population included 16 specimens (18%) obtained from infants, adolescents and young adults ranging in age from 1 month to 29 years, which were evenly divided between males and females. All of the specimens in the clinical studies were frozen prior to testing. The results obtained in these studies are shown below in tables 1 and 2, respectively.

Table 1. Results of Tests of 88 Archival Patient Specimens Tested at an Independent Clinical Laboratory (Laboratory A) Miami, FL, Using the EB VCA IgM EIA Test and Another Commercial IFA Test.

Comparative	EB VCA IgM EIA			
Test #1	Positive	Negative	Equivocal	Total
Positive	29	0	2	31
Negative	3	54	0	57
Equivocal	-	-	-	-
Total	32	54	2	88

Overall agreement [(TP + TN) / (TP + TN + FP + FN)] = 96.5 % *
95% CI = 90.1 to 99.3**

* Excluding equivocal results ** Calculated by the exact method.

Table 2. Results of Tests of 157 Archival Patient Specimens Tested at Laboratory B (Miami, FL) Using the EB VCA IgM EIA Test and Another Commercial EIA Test.

Comparative	EB VCA IgM EIA			
Test #2	Positive	Negative	Equivocal	Total
Positive	26	5	0	31
Negative	3	121	2	126
Equivocal	0	0	0	0
Total	29	126	2	157

Overall agreement [(TP + TN) / (TP + TN + FP + FN)] = 94.8% *
95% CI = 94.8 to 98.3% **

* Excluding equivocal results ** Calculated by the exact method.

Sensitivity and specificity relative to serological profile

One hundred and fifty-seven archival serum specimens (see table 2) were tested at Laboratory B using the EB VCA IgM EIA test, and other commercially available EIA tests for detecting VCA IgG, VCA IgM and EBNA IgG antibodies. One hundred and thirty-nine 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 IgM EIA assay were determined based on these characterizations. It was assumed that the VCA IgM response should be negative for the seronegative samples and the samples from past infections, and positive for the acute samples. The results have been summarized below in table 3.

Table 3. Results of Tests Performed at Laboratory B with 139 Pre-selected Serum Specimens, Using the EB VCA IgM EIA Test, and Other Commercially Available Tests for VCA IgG, VCA IgM and EBNA IgG Antibodies.

	Serum Characterization		
	Acute	Past Infection	Seronegative
EB VCA IgM EIA	VCA IgM + EBNA IgG -	VCA IgM - VCA IgG + EBNA IgG +	VCA IgM - VCA IgG - EBNA IgG -
Positive	26	3	0
Negative	1	96	10
Equivocal	0	3	0
Total	27	102	10

Relative sensitivity (Acute) = 26/27 = 96.3 %, 95 % CI = 81.1 % to 99.9 %*
Relative sensitivity (Seropositive) = 96/99 = 97.0 %, 95 % CI = 91.4 % to 99.4 %*
Relative specificity (Seronegative) = 10/10 = 100 %, 95 % CI = 69.2 % to 100 %*
Relative agreement = 132/136 = 97.1 %, 95 % CI = 92.2 % to 99.9 %*

Equivocal results were not included in the calculations, nor were they retested.
* 95 % confidence intervals (CI) were calculated using the exact method.

Cross-reactivity study

The EB VCA IgM EIA test does not cross-react with antibodies directed against the other herpes viruses: cytomegalovirus, varicella-zoster virus and herpes simplex virus. Thirteen serum specimens which were shown to be negative when assayed with the EB VCA IgM EIA test, were shown to be

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positive for IgM antibodies directed against the other herpes viruses including: 4 containing herpes simplex virus IgM antibody, 4 with cytomegalovirus IgM antibody and 5 with varicella-zoster virus IgM antibody. The herpes IgM and CMV IgM antibodies were detected with IgM-specific enzyme immunoassays and the varicella-zoster IgM antibodies were detected by fluorescent antibody membrane antigen (FAMA) assay. The level of antibodies in these serum specimens was 1.4 to 6.3 times the assay cut-off value of herpes simplex virus IgM assay, 1.7 to 2.2 times the cut-off of the cytomegalovirus assay and 2 to 4 times the cut-off of the varicella-zoster virus assay. These results, shown below in table 4, indicate that the EB VCA IgM EIA test does not cross-react with IgM antibodies directed against the other herpes viruses.

Table 4. Results of EB VCA IgM EIA Assays of Thirteen Serum Specimens Shown to be Positive for IgM Antibodies Directed Against Other Herpes Viruses.

Sample ID	VCA-M Index*√	CMV-M Index*√	HSV-M Index*√	VZV-M Index*√√
Q002-27-150C	0.7, Neg	2.2	ND	ND
Q002-27-150D	0.9, Neg	2.0	ND	ND
Q002-27-150E	0.5, Neg	1.9	ND	ND
Q002-27-150F	0.6, Neg	1.7	ND	ND
Q002-27-170C	0.4, Neg	ND	4.3	ND
Q002-27-170D	0.6, Neg	ND	3.6	ND
Q002-27-170E	0.7, Neg	ND	4.2	ND
Q002-27-170F	0.1, Neg	ND	1.6	ND
Q021-3-1	0.3, Neg	ND	ND	2.0
Q021-3-2	0.5, Neg	ND	ND	4.0
Q021-3-3	0.4, Neg	ND	ND	2.0
Q021-3-4	0.7, Neg	ND	ND	4.0
Q021-3-5	1.0, Equ	ND	ND	4.0

***** Index value = Observed value divided by assay cutoff value
√ Index value ≥ 1.1 = Positive
√√ Index value ≥ 1.0 = Positive
ND Not done

IgM Specificity Study

Five serum specimens which contained EB VCA-specific IgM and EB VCA-specific IgG, were assayed by the EB VCA IgM EIA and EB VCA IgG EIA tests, before and after treatment with 2-mercaptoethanol. This treatment denatures IgM but does not affect IgG antibodies. The results of this experiment are shown in table 5, below.

Table 5. Results Obtained for EB VCA IgM EIA and EB VCA IgG EIA Assays of Five Serum Specimens Containing EB VCA-Specific IgG and IgM, Before and After Treatment with 2-mercaptoethanol.

Sample	VCA IgM Index		VCA IgG Index	
	Before	After	Before	After
1	1.5	0	8.8	9.0
2	2.0	0	1.8	2.3
3	2.2	0	1.7	1.2
4	5.4	1.5	15.1	19.1
5	8.0	0	4.1	3.4

After treatment with 2-mercaptoethanol, the EB VCA IgM antibodies in all five specimens were neutralized, while the EB VCA IgG antibodies were not significantly affected. These results demonstrate that the EB VCA IgM EIA test is specific for detecting EB VCA IgM antibodies.

Precision

Six serum specimens (5 positives and 1 negative) and the EB VCA IgM EIA Positive and Negative Controls, were assayed in triplicate, on three separate occasions. These results are shown below in table 6.

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

	INTRA-ASSAY			INTERASSAY		
SAMPLE	MEAN INDEX	S.D	C.V. %	MEAN INDEX	S.D	C.V. %
Pos. Control	2.2	0.306	14.1	2.1	0.265	12.8
Neg. Control	0.6	0.058	NA	0.5	0.000	NA
1	0.2	0.000	NA	0.2	0.073	NA
2	7.7	0.635	8.3	7.6	0.604	8.0
3	2.7	0.100	3.7	2.7	0.101	3.8
4	3.6	0.379	10.6	3.6	0.273	7.6
5	2.4	0.208	8.6	2.3	0.220	9.5
6	3.0	0.058	1.9	2.8	0.194	6.8

References

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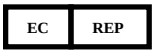
Symbols Glossary

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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