



IMMUNODOT™ MONO-M TEST

 For In Vitro Diagnostic Use

INTENDED USE

The Mono-M Test is a qualitative enzyme immunoassay (EIA) that detects IgM antibodies to Paul-Bunnell heterophil, Epstein-Barr virus capsid antigen (EBV-VCA), and cytomegalovirus (CMV). When used in conjunction with Mono-G Test, it is an aid in the serodiagnosis of infectious (EBV) mononucleosis and presumptive serodiagnosis of CMV mononucleosis-like syndrome. This assay has not been FDA cleared or approved for the screening of blood or plasma donors. Performance with this device has not been established for either prenatal screening or newborn testing. Performance of this assay has not been established in a non-clinical laboratory environment (e.g., point of care testing).

SUMMARY AND EXPLANATION

Mononucleosis is characterized by malaise, fever, hepatosplenomegaly, lymphadenopathy, and abdominal discomfort. Infectious mononucleosis (IM) has multiple etiologies; the most common infectious etiologic agent is Epstein-Barr virus (EBV). Cytomegalovirus (CMV) and *Toxoplasma gondii* infections also may cause mononucleosis syndrome. Mononucleosis caused by EBV is commonly diagnosed serologically by measuring antibodies to the Paul-Bunnell heterophil antigen, but agent specific assays provide more comprehensive laboratory support for diagnosis of mononucleosis syndrome.

ASSAY PRINCIPLE

The assay uses an enzyme-linked immunoassay (EIA) dot technique for the detection of antibodies. Various levels of antigens are provided as discrete dots on the assay strip. Two levels of heterophil antigen are used to increase heterophil detection probability since this serological reaction is most important for accurate IM serodiagnosis. An assay strip is incubated with diluted patient serum, allowing patient antibodies reactive with the test antigens to bind to the solid support membrane. In the second stage, the reaction is enhanced by removal of non-specifically bound materials. During the third stage, alkaline phosphatase-conjugated antihuman antibodies are allowed to react with bound patient antibodies. Finally, the strip is transferred to enzyme substrate reagent which reacts with bound alkaline phosphatase to produce an easily seen, distinct dot.

REAGENTS

Assay Strip: Antigens in order beginning with the window next to the label: Positive reagent control (human serum), Level 1 Heterophil Antigen (purified from bovine red blood cells (more sensitive level), Level 2 Heterophil Antigen (less sensitive level), EBV-VCA (gp125, purified by affinity chromatography), CMV (glycine lysate of strain AD-169) and Negative reagent control

Diluent (#1): Consists of buffered diluent containing IgG absorbent (goat antihuman IgG), protein stabilizers with <0.1% NaN₃

Enhancer (#2): Consists of sodium chloride with <0.1% NaN₃

Conjugate (#3): Consists of alkaline phosphatase conjugated goat antihuman IgM (heavy chain specific) in buffered diluent with <0.1% NaN₃

Developer (#4): Consists of 5-bromo-4-chloro-3-indolyl phosphate and p-nitro blue tetrazolium chloride in buffered diluent with <0.1% NaN₃

WARNINGS AND PRECAUTIONS

For In-Vitro Diagnostic Use. ImmunoDOT reagents have been optimized for use as a system. Do not substitute other manufacturers' reagents or other ImmunoDOT Assay System reagents. Dilution or adulteration of these reagents may also affect the performance of the test. Do not use any kits beyond the stated expiration date. Analytic quality water must be used as water. Close adherence to the test procedure will assure optimal performance. Do not shorten or lengthen stated incubation times since these may result in poor assay performance.

Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. It may be harmful if enough is ingested (more than supplied in kit). On disposal of liquids, flush with a large volume of water to prevent azide build-up (1). This dilution is not subject to GHS, US HCS and EU Regulation 2008/1272/EC labeling requirements.

The safety data sheet (SDS) is available at support.genbio.com or upon request.



Human source material. Material used in the preparation of this product has been tested and found non-reactive for hepatitis B surface antigen (HBsAg), antibodies to hepatitis C virus (HCV), and antibodies to human immunodeficiency virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease (2). Follow recommended Universal

Precautions for bloodborne pathogens as defined by OSHA (3), Biosafety Level 2 guidelines from the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (4), WHO Laboratory Biosafety Manual (5), and/or local, regional and national regulations.

STORAGE

Store reagents and assay strips at 2-8°C. Reagents must be at room temperature (15-30°C) before use. Avoid contamination of reagents. Assuming good laboratory practices are used, opened reagents remain stable as indicated by the expiration date.

SPECIMEN COLLECTION AND HANDLING

ImmunoDOT Test is performed on serum. The test requires 10 µL of serum. Lipemic or hemolyzed serum has not been shown an acceptable specimen.

Store samples at room temperature for no longer than eight hours. If the assay will not be completed within eight hours, refrigerate the sample at 2-10°C. If the assay or shipment of the samples will not be completed within 48 hours, freeze at -20°C.

MATERIALS PROVIDED

Assay Strips	Conjugate (#3)
Diluent (#1)	Developer (#4)
Enhancer (#2)	Reaction Vessels

MATERIALS REQUIRED BUT NOT PROVIDED

Workstation	Timer
Pipets	Specimen collection apparatus (e.g., finger sticking device, venipuncture equipment)
Positive Control serum*	Absorbent toweling to blot dry assay strips
Negative Control serum*	Analytic quality water

*See Quality Control

SET-UP

1. Turn on Workstation and adjust to appropriate temperature if necessary. Refer to Workstation Instructions.
2. Remove 4 Reaction Vessels per test from the product box and insert into appropriate slots in Workstation. For the large Workstation, add water up to the fill line of the water in the provided container. For the small Workstation, use an appropriate container and sufficient water to cover all reactive windows of the assay strip.
3. Place 2 mL Diluent (#1) in Reaction Vessel #1; 2 mL Enhancer (#2) in Reaction Vessel #2; 2 mL Conjugate (#3) in Reaction Vessel #3; and 2 mL Developer (#4) in Reaction Vessel #4.
4. Appropriately label the Assay Strips.
5. If the large Workstation is used, insert the label end of the assay strip into the Strip Holder, one per groove, taking care not to touch the assay windows.

ASSAY PROCEDURE

1. Add 10 µL serum to Reaction Vessel #1.
2. Prewet Assay Strip by immersing in water for 30-60 seconds.
3. Using several (5-10) quick up and down motions with the Assay Strip, mix thoroughly in Reaction Vessel #1. Let stand for 60-90 minutes.
4. Remove Assay Strip from Reaction Vessel and swish in the water. Use a swift back and forth motion for 5-10 seconds allowing for optimal washing of the Assay Strip's membrane windows.
5. Place Assay Strip into Reaction Vessel #2. Mix thoroughly with several (5-10) quick up and down motions. Let stand for 5 minutes.
6. Remove Assay Strip from Reaction Vessel #2 and swish in water as described (step #4).
7. Place Assay Strip into Reaction Vessel #3. Mix thoroughly with several (5-10) quick up and down motions. Let stand for 30-40 minutes.
8. Remove Assay Strip from Reaction Vessel #3 and swish in water as described (step #4). DO NOT remove the Assay Strip from the water.
9. Allow the Assay Strip to stand in the water for 5 minutes.
10. Remove Assay Strip from water and place into Reaction Vessel #4. Mix thoroughly with several (5-10) quick up and down motions. Let stand for 5 minutes.
11. Remove Assay Strip from Reaction Vessel #4 and swish in water as described (step #4).
12. Blot and allow Assay Strip to dry. It is imperative that tests of borderline specimens be interpreted after the Assay Strip has been allowed to dry. A false positive dot may be identified if the assay strip is not dry when interpreted.

READING THE ASSAY STRIP

Positive	A dot with an EASILY SEEN, distinct border is visible in the center of the window. The outer perimeter of the window must be white to pale gray.
Negative	If no dot is seen or a dot is difficult to see, interpret it as negative.

In order to minimize the possibility of "over interpreting" positive test results it is recommended that during initial validation of the assay (as may be required by the laboratory by regulation), the laboratory test a series of presumptive negative samples and each technician interpret the assay strips in a blinded fashion. Please call GenBio Technical Service for further clarification. (To report results, refer to Interpretation Section)

QUALITY CONTROL

The assay's reagent temperature is between 42-48°C. Due to heat transfer loss, the Workstation temperature is set higher. The appropriate Workstation temperature setting is listed in the Workstation's package insert. (Contact Technical Services for additional guidance if an alternate heat source is used.)

In order to ensure precision at the assay cutoff, a control for each analyte with level(s) falling close to the cutoff is recommended. IgG (Product No. 3908) and IgM (Product No. 3909) positive control sera moderately reactive to all analytes are available. A negative control (Product No. 3920) is also available. NCCLS C24-A should be consulted for guidance on appropriate quality control practices. These should be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations. Unless otherwise required, it is recommended that control sera be tested upon receipt of a kit. If the control is not reactive, results should not be reported and GenBio Technical Service should be contacted before the kit is used again.

The kit uses reagent controls to assure performance each time a test is performed. The Positive Control window (well #1) contains human serum and tests reagent reactivity. It must be reactive but the intensity must not be used as a calibrator. As a negative reagent control check, the backgrounds around dots and the bottom window (#6) must be white. If the positive is not reactive or the negative is reactive, do not interpret the assay strip.

INTERPRETATION

NEGATIVE INTERPRETATION

Negative results do not rule out the diagnosis of mononucleosis syndrome. The specimen may be drawn before appearance of detectable antibodies. Negative results in suspected early disease should be repeated within 4-6 weeks.

EBV INTERPRETATION

EBV serodiagnosis uses heterophil, VCA IgM, VCA IgG and EBNA-1 results and classifies the interpretation as current, recent or past infection.

Table 1: EBV Interpretation

Pattern	H1	H2	VCAM	VCAG	EBNA-1	Interpretation
1	+	+	+	+	-	Current Infection
2	+	+	+	-	-	Current Infection
3	+	+	-	-	-	Current Infection
4	+	+	-	+	+	Recent/Past Infection
5	-	-	+	+	+	Recent/Past Infection
6	-	-	-	+	+	Past Infection
7	-	-	-	+	-	Indeterminate †

†This pattern occurred 5% of the time in prospective studies. Two of the 16 samples were negative; six were from current infections and 8 from past or recent infections as defined by the reference methods. If indicated, it is recommended that a later sample (2-3 weeks) be tested.

Table 2 lists less common reactions. These may occur, but if many or most reaction types are these, please contact Technical Service.

Table 2: EBV Interpretation - Less Common Reactions

Pattern	H1	H2	VCAM	VCAG	EBNA-1	Interpretation
8	-	-	+	+	-	Current Infection
9	+	-	+	+	-	Current Infection
10	+	-	-	+	+	Recent/Past Infection

Pattern	H1	H2	VCAM	VCAG	EBNA-1	Interpretation
11	+	-	+	+	+	Recent/Past Infection
12	+	+	+	+	+	Recent/Past Infection
13	-	+	+	+	+	Recent/Past Infection
14	-	-	-	-	+	Past Infection
15	-	+	-	+	+	Past Infection
16	-	+	+	+	-	Indeterminate
17	+	-	-	+	-	Indeterminate †
18	-	+	+	-	-	Indeterminate ‡
19	+	-	-	-	-	Negative

†These patterns were not seen in prospective studies and should be cautiously interpreted. If indicated, it is recommended that a later sample (4-6 weeks) be tested.

‡These patterns should be infrequent and cautiously interpreted. Please contact Technical Service.

EBV serodiagnosis requires both Mono-M and Mono-G results. Two heterophil antibody levels increase detection probability. The levels should not be used to infer the amount (quantitation) of antibody. Should the laboratory desire to quantify the H1 or H2 level it should use an alternative methodology. Other EBV reaction combinations should not be interpreted. If needed, contact Technical Service.

Due to cross reactivity between EBV and CMV, current or recent EBV infections may be CMV IgM reactive. Using serological methods, it is not possible to determine if CMV infection is concurrent. Only consider CMV infection if EBV infection is not detected.

Sera collected for either EBV and/or mononucleosis studies and normal (mononucleosis negative) samples were used to establish cutoffs. The classification by disease stage according to the EBV profile result (heterophil, VCA IgM, VCA IgG, and EBNA-1) was given primary consideration.

CMV INTERPRETATION

Table 3 details CMV interpretation. This is a presumptive result and further testing may be indicated to assure the serodiagnosis of CMV mononucleosis-like syndrome.

Normal (CMV mononucleosis negative) samples and retrospective CMV IgM positive samples were used to assure the CMV cutoff.

Table 3: Presumptive CMV Interpretation

Stage	Mono-G CMV	Mono-M CMV
Recent or Current	+	+
Past	+	-
Negative	-	-

LIMITATIONS

- Cross reactivity testing with this assay for antibodies to other closely related organisms and interference testing for RF and/or anti-nuclear antibodies has not been performed.
- ImmunoDOT Mono-M or Mono-G is not designed to assess immune status to EBV, CMV or *Toxoplasma* nor has the test been evaluated in immunosuppressed or immunocompromised individuals.
- Performance in young children (under 12 years old) was not fully evaluated.
- The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy. It is designed for serodiagnosis of IM using the profiles described in the Interpretation section.
- Negative results do not rule out the diagnosis of disease because the specimen may be drawn before appearance of detectable antibodies. However, results in suspected early infection should be repeated within 4-6 weeks.
- Assay performance characteristics have not been established for matrices other than serum.
- The IgG absorbent in Diluent #1 removes up to 15 mg/mL of human IgG (50% endpoint), but the presence of residual IgG in individuals with hyper-gammaglobulinemia may affect results adversely.
- Prevalence of an antibody will affect the assay's predictive value.
- IgM antibody results obtained from the assay are an aid to diagnosis only.
- In most cases, a positive antibody result will provide laboratory support of infection. However, specific IgM may persist for several months after initial infection. Each physician must interpret these results in light of the patient's history and physical findings.

- Testing should not be performed as a screening procedure for the general population. The predictive value of a positive or negative serologic result depends on the pretest likelihood of infectious mononucleosis (the various analytes included in this assay) being present. Testing should only be done when clinical evidence suggests the diagnosis of infectious mononucleosis syndrome.
- The performance of this device has not been established for semi-quantitative utility of H1 and H2.

EXPECTED RESULTS

ImmunoDOT detects specific antibodies of three organisms that may cause mononucleosis or mononucleosis-like syndrome. EBV is the predominant cause and CMV is the second most frequent cause of mononucleosis. In the U.S., toxoplasmosis causing a mononucleosis-like syndrome is rare.

EBV MONONUCLEOSIS

Heterophil: Primary EBV infections in early infancy (less than two years old) are typically inapparent. The heterophil antibody response is barely significant and the infection is silent and shows at most minor hematologic changes (6) (7) (8). The incidence of heterophil antibody responses in the 2 to 5 year old age range is, at most, slightly lower than in adolescents or young adults when sensitive assays are employed. However, the heterophil antibody titers, while covering similar ranges in all age groups, are nevertheless found to increase generally with advancing age. The relatively low heterophil antibody titers of young children explain why such responses may be missed in assays of limited sensitivity, especially rapid slide tests with sheep RBC stromata. Should the laboratory desire to quantify the H1 or H2 level it should use an alternative methodology.

VCA: Sumaya and Ench (9) report VCA IgM sensitivity at 86% in children under 18 years old. The mean titer was higher in older (4 to 16 years old) than younger (less than 4 years old) children. Lennette (10) reports that 10-15% of EBV mononucleosis patients have no detectable VCA IgM by the time of the first serum collection, but both IgG and IgM are typically detectable within 2-3 weeks of onset and peak at 4-6 weeks. IgM VCA disappears rapidly while IgG-VCA wanes slightly and then varies little for life.

EBNA: Anti-EBNA-1 accounts for essentially all of the anti-EBNA in convalescent or later phase sera as measured by the conventional ACIF assay using Raji cells, yet anti-EBNA-2A are the dominant antibodies during the first five months after onset of primary infection (11).

CMV MONONUCLEOSIS

CMV as the cause of mononucleosis has been described since 1969. Friedman reports that CMV is responsible for about 8% of all mononucleosis (12). Lajo, et al. (13) prospectively examined 124 pediatric mononucleosis patients, 12 years old and younger, and reports that 16% of these mononucleosis cases were caused by CMV. Evans (14) reports that 45% of the cases of CMV mononucleosis occurred over the age of 30 years.

TOXOPLASMOSIS (MONONUCLEOSIS-LIKE)

Detection of IgG-specific *Toxoplasma* antibodies is rarely problematic, but low assay specificity of IgM-specific antibodies is reported (15). The incidence of IgG-specific antibody in the U.S. is typically low and the incidence of toxoplasmosis mononucleosis-like syndrome is also rare in the U.S.

PROSPECTIVE STUDY RESULTS

Three hundred two samples submitted for mononucleosis serology testing at two laboratories were evaluated. Site A, a national reference laboratory, tested 186 samples and site B, a Midwestern U.S. city hospital laboratory, tested 116 samples. The reference Paul-Bunnell heterophil assay, EBV, CMV and *Toxoplasma* specific serology tests were conducted at an outside reference laboratory. A statistical description of the study populations is shown in Table 4. It should be noted that subjects at the Site A study were younger (median = 17) than subjects at Site B (median = 24). ImmunoDOT performance in this prospective study is shown in the following section (see Performance Characteristics).

Table 4: Population Statistics

Statistic	Site A	Site B	Combined
Number of Samples Tested	186	116	302
Average Age	22.8	27.0	24.4
Median Age	17	24	19
Male/Female ratio	0.73	0.63	0.69
Minimum Age	<1	2	<1
Maximum Age	79	73	79

The age distribution of these cases is shown in Table 5. The average age is 29.8.

Table 5: Age Distribution of EBV IM Cases in Prospective Study

Age Range (years)	Site A	Site B	Combined (%)
>50	1	0	1 (3%)
18-50	8	1	9 (25%)
12-18	14	7	21 (58%)
8-12	1	0	1 (3%)
<8	1	3	4 (11%)

The Incidence of ImmunoDOT results at the two sites is shown in Table 6.

Table 6: Prospective Study Results - EBV Infections Only

Classification	Site A	Site B	Combined
Negative	18%	8%	14%
Current	14%	10%	13%
Past/Recent	61%	79%	68%
Indeterminate	7%	3%	5%

ImmunoDOT identified five (12%) additional CMV mononucleosis cases and no toxoplasmosis cases. These observations are consistent with published expectations; however, results in each laboratory may vary due to patient selection criteria, average age of subjects, and various other epidemiological factors.

PERFORMANCE CHARACTERISTICS

A prospective study was performed to assess assay performance. The study and population statistics are described in the previous section, Expected Results. Site A information based on profile comparison is presented in Table 7. Site B information is shown in Table 8 and the combined data can be seen in Table 9.

Table 7: Site A EBV Performance

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	33	0	1
Current	2	23	1
Past/Recent	0	1	112
Indeterminate	0	6	7

Table 8: Site B EBV Performance

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	9	0	0
Current	1	10	1
Past/Recent	0	0	92
Indeterminate	2	0	1

Table 9: EBV Performance Summary

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	42	0	1
Current	3	33	2
Past/Recent	0	1	204
Indeterminate	2	6	8

There were no *Toxoplasma* IM cases identified during the prospective trial period. Two CMV mononucleosis cases at Site A and three CMV mononucleosis cases at Site B were observed. Three of the five sera from presumptive CMV mononucleosis cases were positive according to reference results. These CMV results are included as ImmunoDOT current positives in Table 10: Overall Performance Summary which summarizes overall ImmunoDOT performance.

Table 10: Overall Performance Summary

ImmunoDOT	Reference Results		
	Negative	Current	Past/Recent
Negative	42	0	1
Current	5	36	2
Past/Recent	0	1	199
Indeterminate	2	6	8

Using the above information, assay performance characteristics are shown in Table 11. Indeterminate results are not used for the calculations.

Table 11: Performance Characteristics

	Sensitivity	Sensitivity Range	Specificity	Specificity Range
EBV Infectious Mononucleosis	99.6% (240/241)	97.7-100%	93% (42/45)	93-99%
Mononucleosis Syndrome	98.7% (236/239)	96-99.7%	89% (42/47)	77-96%

PRECISION DATA

The intensity of the dot is directly related to precision. The darkest dots are most reliable while weaker reactions are proportionately less reliable. Site A and Site B laboratories were supplied masked specimens containing mixtures of the various analytes. Therefore, not all analytes tested the same number of replicates. Testing was conducted in triplicate each day. Tests were performed on six different days. The results (Table 12 and Table 13) show adequate qualitative discrimination for each analyte.

Table 12: ImmunoDOT Mono M Precision Results

Antibody Level	Level 1 Heterophil	Level 2 Heterophil	VCA IgM	CMV IgM
Moderate	100% (36/36)	100% (36/36)	100% (36/36)	100% (72/72)
Low	100% (108/108)	100% (108/108)	100% (72/72)	100% (144/144)

Table 13: ImmunoDOT Mono G Precision Results

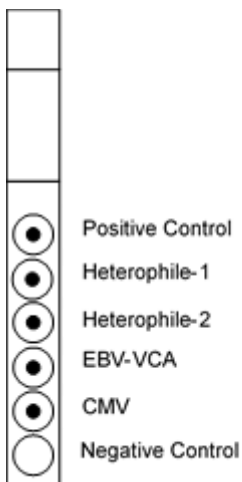
Antibody Level	VCA IgG	EBNA IgG	CMV IgG	Toxoplasma IgG \ddot{S}
Moderate	100% (144/144)	100% (36/36)	100% (144/144)	100% (72/72)
Low	100% (72/72)	100% (144/144)	100% (72/72)	85% (122/144)

Moderate is greater than or equal to 1:128 IFA titer. Low is less than 1:50 IFA titer.

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QUICK REFERENCE PROCEDURE

IMMUNODOT MONO-M

Set-Up

- Make sure Workstation is at temperature.
- Place reaction Vessels into slots in Workstation and add water to the rinse container.
- Place 2 mL Diluent (1) in Vessel #1; 2 mL Enhancer (2) in Vessel #2; 2 mL Conjugate (3) in Vessel #3; and 2 mL Developer (4) in Vessel #4.

Procedure

- Add 10 µL serum to Vessel #1.
- Prewet assay strip in water for 30 - 60 seconds.
- Place strip in Vessel #1, mix, let stand 60-90 min.
- Remove strip, place in water, swish 5-10 sec.
- Place strip in Vessel #2, mix, let stand 5 min.
- Remove strip, place in water, swish 5-10 sec.
- Place strip in Vessel #3, mix, let stand 30-40 min.
- Remove strip, place in water, let stand 5 min.
- Place strip in Vessel #4, mix, let stand 5 min.
- Remove strip, place in water, swish, blot, dry, and read

To place an order for ImmunoDOT products, contact your local distributor, or call GenBio directly for the distributor nearest you and for additional product information.
 For assistance, please call toll-free 800-288-4368.



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