BIO-RAD

MAY - 3 2007

MONOLISA™ Anti-HAV EIA 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:	K 063318
510(k) Summary Report Date:	April, 2007

MANUFACTURER INFORMATION

MANUFACTURER ADDRESS:	Bio-Rad 3, Boulevard Raymond Poincaré 92430 Marnes-la-Coquette, France
TELEPHONE :	00 33 1 47 95 60 00
ESTABLISHMENT REG. NUMBER :	8023060
OWNER/OPERATOR :	Bio-Rad 3, Boulevard Raymond Poincaré 92430 Marnes-la-Coquette, France
OWNER/ OPERATOR NUMBER :	8023061
OFFICIAL CORRESPONDENT ADDRESS :	Bio-Rad 3, Boulevard Raymond Poincaré 92430 Marnes-la-Coquette, France
TELEPHONE:	00 33 1 47 95 60 00
OFFICIAL CORRESPONDENT :	Mrs. Sylvie Confida
TELEPHONE : **FAX :**	00 33 1 47 95 61 38 00 33 1 47 95 62 42

CLASSIFICATION INFORMATION

CLASSIFICATION NAME:	Hepatitis A Test (Total Antibody)
COMMON NAME:	Total Antibody to Hepatitis A Virus
PRODUCT TRADE NAME:	MONOLISA™ Anti-HAV EIA
DEVICE CLASS :	Class II LOL

CLASSIFICATION PANEL : Immunology and Microbiology Devices

REGULATION NUMBER : 21 CFR 866.3310

LEGALLY MARKETED EQUIVALENT (SE) DEVICE

DiaSorin ETI-AB-HAVK PLUS
PMA Number : P890019
Decision Date : 12/12/2005

DEVICE DESCRIPTION

The MONOLISA™ Anti-HAV EIA is an enzyme immunoassay (competitive assay format) for the detection of total antibodies to Hepatitis A virus. In the assay procedure, patient specimens, a calibrator and controls are incubated with HAV antigen in microwells that have been coated with mouse monoclonal anti-Hepatitis A antibodies. Antibodies to HAV present in a specimen or control will complex with the HAV antigen reagent and with antibodies coated on the microwells. Excess sample and HAV Viral antigen reagent are removed by a wash step. The conjugate (containing horseradish peroxidase-labeled mouse monoclonal antibody to HAV) is subsequently added to the microwells and incubated. The conjugate binds to the HAV antigen bound to the microwell in the absence of antibodies to HAV from the specimen. Excess conjugate is removed by a wash step, and a TMB Chromogen / Substrate solution is added to the microwells and allowed to incubate. If a sample does not contain anti-HAV antibodies, the bound enzyme (HRP) causes the colorless tetramethylbenzidine (TMB) in the Chromogen solution to change to blue. The blue color turns yellow after the addition of a Stopping Solution. If a sample contains anti-HAV antibodies, the Chromogen / Substrate Solution in the well remains colorless during the substrate incubation, and after the addition of the Stopping Solution. The color intensity is measured spectrophotometrically.

Absorbance value readings for patient specimens are compared to the Cutoff value determined by the mean of the Calibrator absorbance values.

BIO-RAD

KIT COMPONENTS

Component	Description
R1 Microwell Strip Plates	Two (2) x 12 strips of 8 wells coated with monoclonal anti-HAV antibodies.
R2 Wash Solution Concentrate (30x)	One (1) 120 mL bottle, Tris-buffer containing NaCl and Tween 20.
C0 Negative Control	One (1) 1.5 mL vial, containing human serum, negative for total anti-HAV antibodies, HBs antigen, anti-HCV antibodies and anti-HIV-1/ HIV-2 antibodies. Preservatives : Sodium azide (< 0.1%) and Proclin™ 300 (0.25%).
C1 Positive Control	One (1) 1.5 mL vial, containing human serum, positive for anti-HAV antibodies and negative for HBs antigen, anti-HCV antibodies and anti-HIV-1/HIV-2 antibodies, diluted in human serum pool negative for anti-HAV antibodies. Preservatives : Sodium azide (< 0.1%) and Proclin™ 300 (0.25%).
C2 Calibrator	Two (2) x 1.5 mL vials, containing human serum, positive for anti-HAV antibodies, and negative for HBs Antigen, anti-HCV antibodies and anti-HIV-1/HIV-2 antibodies, diluted in human serum pool negative for anti-HAV antibodies. Preservatives : Sodium azide (< 0.1%) and Proclin™ 300 (0.25%).
R6 HAV Viral Antigen	Two (2) x 14 mL bottles, inactivated HAV virus in Tris buffer containing proteins and sample indicator dye. Preservative : Proclin™ 300 (0.1%).
R7 Conjugate	Two (2) x 14 mL bottles, conjugate (Peroxidase labeled mouse monoclonal antibody to HAV) in Tris buffer containing proteins, detergent and sample indicator dye. Preservative : Proclin™ 300 (0.1%).
R8 Substrate Buffer	One (1) 120 mL bottle, containing Hydogen Peroxide, citric acid / sodium acetate buffer and Dimethylsulfoxide (DMSO).
R9 Chromogen (11x)	One (1) 12 mL bottle, containing Tetramethylbenzidine (TMB).
R10 Stopping Solution	One (1) 120 mL bottle, containing 1 N H_2SO_4.
Plate sealers	Eight (8) clear plastic sealers.

BIO-RAD

INTENDED USE

The MONOLISA™ anti-HAV EIA is an *in vitro* enzyme immunoassay kit intended for use in the qualitative detection of total antibodies (anti-HAV IgG and IgM) to Hepatitis A virus (anti-HAV) in human (adult and pediatric) serum or plasma (EDTA, Heparin, Citrate, ACD.

This assay is not intended for screening blood or solid or soft tissue donors.

INDICATIONS FOR USE

The MONOLISA™ anti-HAV EIA is indicated for use as an aid in the diagnosis of acute or past Hepatitis A Virus (HAV) infection or as an aid in the identification of HAV-susceptible individuals for vaccination. However, any diagnosis should take into consideration the patient's clinical history and symptoms, as well as serological data.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, and core blood or neonatal specimens.

TECHNOLOGICAL CHARACTERISTICS

The following tables summarize similarities and differences between the MONOLISA™ Anti-HAV EIA kit and the predicate device ETI-AB-HAVK PLUS.

Table 1: Similarities between kit components and materials

Similarities in Components / Materials	**MONOLISA™ Anti-HAV EIA Catalog# 72496**	**ETI-AB-HAVK PLUS Catalog# P001926**
Solid Phase	Microplate wells coated with mouse Monoclonal anti-HAV antibodies.	Microplate wells coated with mouse Monoclonal anti-HAV antibodies.
Conjugate	Peroxidase-labeled mouse monoclonal antibody to HAV.	Peroxidase-labeled mouse monoclonal antibody to HAV.
Negative Control	Human serum, negative for total anti-HAV antibodies.	Human serum/plasma, negative for total anti-HAV antibodies.
Calibrator	Human serum, positive for anti-HAV antibodies, diluted in human serum pool negative for anti-HAV antibodies.	Human serum/plasma, containing anti-HAV antibodies.
Positive Control	Human serum, positive for anti-HAV antibodies, diluted in human serum pool negative for anti-HAV antibodies.	Human serum/plasma, reactive for anti-HAV antibodies.
Chromogen	Tetramethylbenzidine (TMB)	Tetramethylbenzidine (TMB)

Substrate	Hydrogen Peroxide	Hydrogen Peroxide
Washing Solution	Concentrated buffered solution with Tween 20.	Concentrated buffered solution with detergents.

Table 2: Differences between kit components and materials

Differences in Components / Materials	**MONOLISA™ Anti-HAV EIA Catalog# 72496**	**ETI-AB-HAVK PLUS Catalog# P001926**
Conjugate	Ready-to-use.	To be diluted.
Incubation buffer	NA	Buffer, containing protein stabilizers and an inert blue dye.
Viral Antigen / Neutralizing Solution	Tris-buffer, containing inactivated HAV-virus, proteins and sample indicator dye.	Buffer, containing HAV, human serum/plasma and protein stabilizers.
Stopping Solution	1N H_2SO_4.	0.4N H_2SO_4.

Table 3: Similarities between kits with regard to function and use

Similarities in Function and Use	**MONOLISA™ Anti-HAV EIA Catalog# 72496**	**ETI-AB-HAVK PLUS Catalog# P001926**
Test Method	EIA (competitive assay format)	EIA (competitive test)
Format	96-well microplate	96-well microplate
Intended Use	Assay for the qualitative detection of total anti-HAV antibodies in human serum or plasma.	Assay for the qualitative detection of total anti-HAV antibodies in human serum or plasma.
Required sample volume	50 µl	50 µl
Specimen Storage Requirements	Samples may be stored at 2-8 °C for up to 24 hours.	Samples may be stored at 2-8 °C for up to 24 hours.
Calibrator	Referenced to WHO Anti-Hepatitis A Immunoglobulin 2nd International Standard.	Referenced to WHO Anti-Hepatitis A Immunoglobulin 2nd International Standard.
Wavelength	Dual wavelength reading at 450 nm and 615/630 nm.	Dual wavelength reading at 450 nm and 630 nm.
Interpretation of results	Obtained absorbance value readings for patient specimens are compared to the cut-off value determined by the mean of the calibrator absorbance values.	Obtained absorbance readings for patient specimens are compared to a cut-off value determined from the mean of the calibrator absorbance values.

Table 4: Differences between kits with regard to function and use

Differences in Function and Use	**MONOLISA™ anti-HAV EIA Catalog# 72496**	**ETI-AB-HAVK PLUS Catalog# P001926**
Spectrophotometric Verification of Sample and Reagent Pipeting	Possible (but optional)	NA

BIO-RAD

EXPECTED VALUES

Healthy individuals

The expected results of the MONOLISA™ Anti-HAV EIA assay were determined in presumably healthy individuals from the Mid-west US (St Louis, Missouri), the Western US (California and Washington) and from Europe (Parma, Italy).

In the Mid-west, the population was 55% female and 45% male, with ages ranging from 1 to 96 years. 48% (134) were pediatric specimens.

The majority of the subjects were White/Caucasian (64%), and 32% were black or African American; for 4% data were not available.

In this study, 41 % were found reactive for Anti-HAV total antibodies, and 57% were found nonreactive.

In the Western US, 73% were from California, 27% were from Washington. The population was 56% female and 44% male, and their ages ranged from 15 to 90 years.

In this population, 38% were found reactive for Anti-HAV total antibodies, and 62% were found nonreactive.

In Europe, the population was 50% female and 50% male, with ages ranging from 18 to 87 years. In this group, 69% were found reactive for Anti-HAV total antibodies and 31% were found nonreactive.

The expected results for the US and for presumably healthy individuals living in Europe are presented below (Tables 5, 6 and 7).

Table 5: Expected Results for MONOLISA™ Anti-HAV EIA in subjects from the Mid-west US (N= 280)

MONOLISA™ Anti-HAV EIA								
Age Range	Gender	Reactive		Borderline		Nonreactive		Total
		N	%	N	%	N	%	
< 10	Female	10	28.6%	0	N/A	25	71.4%	35
	Male	7	18.4%	2	5.3%	29	76.3%	38
10 -19	Female	14	36.8%	2	5.3%	22	57.9%	38
	Male	9	39.1%	0	N/A	14	60.9%	23
20- 29	Female	3	60.0%	0	N/A	2	40.0%	5
	Male	3	100.0%	0	N/A	0	N/A	3
30 -39	Female	5	50.0%	0	N/A	5	50.0%	10
	Male	3	33.3%	0	N/A	6	66.7%	9
40 -49	Female	3	23.1%	0	N/A	10	76.9%	13
	Male	4	50.0%	0	N/A	4	50.0%	8
50 -59	Female	10	55.6%	0	N/A	8	44.4%	18
	Male	8	47.1%	0	N/A	9	52.9%	17
60 -69	Female	8	57.1%	0	N/A	6	42.9%	14
	Male	4	30.8%	0	N/A	9	69.2%	13
70-79	Female	6	66.7%	1	11.1%	2	22.2%	9
	Male	5	83.3%	0	N/A	1	16.7%	6
80-89	Female	9	69.2%	0	N/A	4	30.8%	13
	Male	3	50.0%	0	N/A	3	50.0%	6
>=90	Female	0	N/A	0	N/A	0	N/A	0
	Male	1	50.0%	0	N/A	1	50.0%	2
Total		**115**	**41.1%**	5	**1.8%**	160	**57.1%**	**280**

BIO-RAD

Table 6: Expected Results for MONOLISA™ Anti-HAV EIA in subjects from the Western US (N= 245)

MONOLISA™ Anti-HAV EIA								
Age Range	**Gender**	**Reactive**		**Borderline**		**Nonreactive**		**Total**
		N	**%**	**N**	**%**	**N**	**%**	
<19	Female	3	60.0%	0	N/A	2	40.0%	5
	Male	1	20.0%	0	N/A	4	80.0%	5
20- 29	Female	11	42.3%	0	N/A	15	57.7%	26
	Male	5	20.8%	0	N/A	19	79.2%	24
30 -39	Female	10	50.0%	0	N/A	10	50.0%	20
	Male	5	27.8%	0	N/A	13	72.2%	18
40 -49	Female	6	33.3%	0	N/A	12	66.7%	18
	Male	10	45.5%	0	N/A	12	54.5%	22
50 -59	Female	15	38.5%	1	2.6%	23	59.0%	39
	Male	5	23.8%	0	N/A	16	76.2%	21
60 -69	Female	6	50.0%	0	N/A	6	50.0%	12
	Male	4	33.3%	0	N/A	8	66.7%	12
70-79	Female	1	11.1%	0	N/A	8	88.9%	9
	Male	1	50.0%	0	N/A	1	50.0%	2
80-89	Female	6	100%	0	N/A	0	N/A	6
	Male	3	75.0%	0	N/A	1	25.0%	4
>=90	Female	0	N/A	0	N/A	1	100.0%	1
	Male	0	N/A	0	N/A	0	N/A	0
Unknown	Female	0	N/A	0	N/A	1	100.0%	1
Total		**92**	**37.6%**	**1**	**0.4%**	**152**	**62.0%**	**245**

BIO-RAD

Table 7: Expected Results for MONOLISA™ Anti-HAV EIA in subjects from Italy, Europe (N= 285)

MONOLISA™ Anti-HAV EIA								
Age Range	Gender	Reactive		Borderline		Nonreactive		Total
		N	%	N	%	N	%	
< 19	Female	0	N/A	0	N/A	1	100.0%	1
	Male	0	N/A	0	N/A	1	100.0%	1
20-29	Female	1	33.3%	0	N/A	2	66.7%	3
	Male	0	N/A	0	N/A	2	100.0%	2
30-39	Female	1	14.3%	0	N/A	6	85.7%	7
	Male	2	28.6%	0	N/A	5	71.4%	7
40-49	Female	7	33.3%	0	N/A	14	66.7%	21
	Male	3	15.8%	0	N/A	16	84.2%	19
50-59	Female	10	45.5%	0	N/A	12	54.5%	22
	Male	14	51.9%	0	N/A	13	48.1%	27
60-69	Female	37	86.0%	0	N/A	6	14.0%	43
	Male	23	85.2%	0	N/A	4	14.8%	27
70-79	Female	31	96.9%	0	N/A	1	3.1%	32
	Male	32	86.5%	0	N/A	5	13.5%	37
80-89	Female	13	100.0%	0	N/A	0	N/A	13
	Male	23	100.0%	0	N/A	0	N/A	23
Total		**197**	**69.1%**	0	**N/A**	**88**	**30.9%**	**285**

BIO-RAD

Adult Subjects At High Risk For Viral Hepatitis:

Expected results of asymptomatic prospective high-risk subjects, determined from a multi-center study in the US and in Europe, are reported in the following tables.

A total of 230 US subjects were at high risk for viral hepatitis including intravenous drug users (N= 55), homosexual males (N=15), sex workers (N=39), prison history (N= 92), high-risk sex partners (N=25), and high-risk occupation/health care workers (N=4). Many had more than 1 high-risk behavior or risk factor. Subjects were from Los Angeles, CA, (86.5%), Santa Ana, CA (4.3%), or Miami, FL (9.1%). The group was Caucasian (7.4%), Black or African American (74.3%), Hispanic or Latino (15.2%), Asian (0.4%), Native Hawaiian or other Pacific Islander (0.4%), and American Indian or Alaska native (0.9%), with the remaining (1.3%) represented by multiple ethnic groups.
Of these subjects, 81% were male and 19% were female, and they ranged in age from 18 to 70 years (mean age of 45). The data are reported in Table 8.
The percent of Anti-HAV reactive results with MONOLISA™ Anti-HAV EIA in this high-risk asymptomatic population was 53%.

The European group (N= 62) was 87% male and 13% female, and ranged in age from 21 to 75 years (mean age of 40). It consisted of intravenous drug users (30), subjects who had clotting factor disorders (7) and MSM patients (25). The data are reported in Table 9.
The percent of Anti-HAV reactive results with MONOLISA™ Anti-HAV EIA in this high-risk asymptomatic population was 45%.

Table 8: Expected results for MONOLISA™ Anti-HAV EIA in the US High Risk Group for Viral Hepatitis A (N=230)

		MONOLISA™ Anti-HAV EIA						
Age Range	**Gender**	**Reactive**		**Borderline**		**Nonreactive**		**Total**
		N	**%**	**N**	**%**	**N**	**%**	
< 19	Female	1	100.0%	0	N/A	0	N/A	1
	Male	1	100.0%	0	N/A	0	N/A	1
20-29	Female	1	33.3%	0	N/A	2	66.7%	3
	Male	1	50.0%	0	N/A	1	50.0%	2
30-39	Female	4	57.1%	0	N/A	3	42.9%	7
	Male	12	33.3%	0	N/A	24	66.7%	36
40-49	Female	15	62.5%	0	N/A	9	37.5%	24
	Male	37	43.5%	1	1.2%	47	55.3%	85
50-59	Female	6	85.7%	0	N/A	1	14.3%	7
	Male	31	60.8%	1	2.0%	19	37.3%	51
60-69	Female	1	100.0%	0	N/A	0	N/A	1
	Male	9	90.0%	0	N/A	1	10.0%	10
70-79	Female	0	N/A	0	N/A	0	N/A	0
	Male	2	100.0%	0	N/A	0	N/A	2
Total		**121**	**52.6%**	**2**	**0.9%**	**107**	**46.5%**	**230**

BIO-RAD

Table 9: Expected results for MONOLISA™ Anti-HAV EIA in the European High Risk Group for Viral Hepatitis A (N=62)

MONOLISA™ Anti-HAV EIA								
Age Range	Gender	Reactive		Borderline		Nonreactive		Total
		N	%	N	%	N	%	
< 19	Female	0	N/A	0	N/A	0	N/A	0
	Male	0	N/A	0	N/A	0	N/A	0
20-29	Female	0	N/A	0	N/A	5	100.0%	5
	Male	0	N/A	0	N/A	11	100.0%	11
30-39	Female	1	50.0%	0	N/A	1	50.0%	2
	Male	5	35.7%	0	N/A	9	64.3%	14
40-49	Female	1	100.0%	0	N/A	0	N/A	1
	Male	9	64.3%	0	N/A	5	35.7%	14
50-59	Female	0	N/A	0	N/A	0	N/A	0
	Male	9	81.8%	0	N/A	2	18.2%	11
60-69	Female	0	N/A	0	N/A	0	N/A	0
	Male	1	50.0%	0	N/A	1	50.0%	2
70-79	Female	0	N/A	0	N/A	0	N/A	0
	Male	2	100.0%	0	N/A	0	N/A	2
>80	Female	0	N/A	0	N/A	0	N/A	0
	Male	0	N/A	0	N/A	0	N/A	0
Total		**28**	**45.2%**	**0**	**N/A**	**34**	**54.8%**	**62**

BIO-RAD

PERFORMANCE CHARACTERISTICS

Clinical performance

A multi-center prospective and retrospective study was conducted to evaluate the clinical performance of the MONOLISA™ Anti-HAV EIA assay among individuals with signs or symptoms and those at high risk of Hepatitis infection. Specimens were collected in 3 different geographical areas: 404 specimens were collected in the US and 928 were collected in Europe (France and Italy).

The US population consisted of 174 subjects with signs and symptoms of Hepatitis.
Of these, 60% were male and 40% were female, and they ranged in age from 17 to 72 years (mean age of 38). The group was Caucasian (13.2%), Black or African American (4.6%), Hispanic or Latino (2.9%), and Asian (41.9%), with 1.1% represented by multiple ethnic groups. The remaining 36.8% were unknown. Among these 174 subjects, 23 (13.2%) were pediatric samples.

The 230 subjects from the high-risk group for Hepatitis A include intravenous drug users (N= 55), homosexual males (N=15), sex workers (N=39), prison history (N= 92), high-risk sex partners (N=25), and high-risk occupation/health care workers (N=4). Many had more than 1 high-risk behavior or risk factor. The group was Caucasian (7.4%), Black or African American (74.3%), Hispanic or Latino (15.2%), Asian (0.4%), Native Hawaiian or other Pacific Islander (0.4%), and American Indian or Alaska native (0.9%), with the remaining (1.3%) represented by multiple ethnic groups. Of these, 81% were male and 19% were female, and they ranged in age from 18 to 70 years (mean age of 45). Among these 230 subjects, 2 (0.9%) were pediatric samples.

The European population consisted of 252 specimens collected from patients with signs and symptoms of Hepatitis. Of these, 51% were male and 49% were female, and they ranged in age from 1 to 105 years (mean age of 53).
Sixty-two (62) specimens were collected from a population at high risk for hepatitis composed of intravenous drug users (30), subjects who had clotting factor disorders (7) and MSM patients (25). The group was 87% male and 13% female, and ranged in age from 21 to 75 years (mean age of 40).
Three hundred and forty five (345) specimens were from an asymptomatic hospitalized population. Of these, 51% were male and 49% were female, and they ranged in age from 18 to 87 years (mean age of 59).
Thirfty four (34) specimens were from healthcare workers (for HAV pre-vaccination screening).
One hundred and fifty one (151) patients had recovered HAV infection.
Among these 844 european samples, 35 (4.1%) were from pediatric subjects.

Vaccinated subjects:
Sixty-two (62) pre- and post-vaccination samples from 38 individuals were tested. Fourteen (14) individuals were enrolled in a vaccination program. They received the TWINRIX® vaccine, a combined Hepatitis A and Hepatitis B vaccine from GlaxoSmithKline. A pre-vaccination sample was collected the day of the first vaccination dose. A second sample was collected before the second vaccination dose was injected (one month after the first dose). A third dose of vaccine was scheduled 6 months after the first injection. The sample after the third vaccination dose was not available.

Twenty (20) samples were collected from 10 subjects, aged 24 to 45 years, who had received the HAVRIX® vaccine. These subjects received HAVRIX® 1440, an inactivated Hepatitis A vaccine from GlaxoSmithKline, in a two-dose schedule (at 0 and 6 to 12 months). For each subject, a pre- and a post-vaccination specimen was obtained. All post-vaccination samples were obtained 4 weeks after vaccination.

Fourteen (14) purchased post-vaccination samples were tested; 8 were from individuals vaccinated with HAVRIX® and 6 were from individuals vaccinated with VAQTA® from Merck &Co.

Percent Agreement

The results obtained with MONOLISA™ Anti-HAV EIA were compared with the results obtained using the comparative assay.

The positive and negative percent agreements and the 95% exact confidence between MONOLISA™ Anti-HAV EIA and the comparative assay were calculated.

To determine the percent agreement on borderline results the following criteria were used:

- Specimens that were borderline with the comparative assay and reactive with MONOLISA™ Anti-HAV EIA were considered as false positives for MONOLISA™ Anti-HAV EIA assay.
- Specimens that were borderline with the comparative assay and nonreactive with MONOLISA™ Anti-HAV EIA were considered as false negatives for MONOLISA™ Anti-HAV EIA.

The results obtained with the US specimens and with the European specimens are presented in the following tables.

Table 10: MONOLISA™ Anti-HAV EIA versus the comparative assay Results in the US Population (N=404)

Subject category	Comparative assay: Positive			Comparative assay Borderline			Comparative assay: Negative			Total
	MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			
	R	BRD	NR	R	BRD	NR	R	BRD	NR	
Subjects with signs and symptoms	123	0	2	1	0	0	1	3	44	174
Subjects with high risk for Hepatitis	114	0	0	2	1	1	4	1	107	230
Total	**237**	**0**	**2**	**3[b]**	**1[d]**	**1[c]**	**5**	**4[a]**	**151**	**404**

	Positive percent agreement	95% Exact Confidence interval	Negative percent agreement	95% Exact Confidence interval
Total	**98,8% (237/240)**	**96.4 – 99.7**	**92.6% (151/163)**	**87.5 – 96.1**

R : Reactive, NR : Nonreactive, BRD : Borderline

[a] : the Borderline results with MONOLISA™ Anti-HAV EIA were considered as false positives.

[b]: the specimens that were Borderline with the comparative assay and reactive with MONOLISA™ Anti-HAV EIA were considered as false positives with MONOLISA™ Anti-HAV EIA.

[c]: the specimens that were Borderline with the comparative assay and nonreactive with MONOLISA™ Anti-HAV EIA were considered as false negative with MONOLISA™ Anti-HAV EIA.

[d]: the results that were borderline with both the MONOLISA™ Anti-HAV EIA and with the comparative assay were not included in the negative agreement or the positive agreement calculations.

Table 11: Comparison of Results for MONOLISA™ Anti-HAV EIA versus the comparative assay in the European Population (N= 844)

Subject category	Comparative assay: Positive			Comparative assay: Borderline			Comparative assay: Negative			Total
	MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti- HAV EIA			MONOLISA™ Anti-HAV EIA			
	R	BRD	NR	R	BRD	NR	R	BRD	NR	
General hospitalized population	236	0	1	0	0	0	0	0	108	345
Sign / Symptoms of Hepatitis	190	0	0	0	2	1	1	1	57	252
Subjects with high risk for Hepatitis	28	0	0	0	0	0	0	0	34	62
Healthcare workers	6	0	0	0	0	0	0	0	28	34
Infected/ recovered HAV	150	0	0	1	0	0	0	0	0	151
Total	**610**	**0**	**1**	**1[b]**	**2[d]**	**1[c]**	**1**	**1[a]**	**227**	**844**

	Positive percent agreement	95% Exact Confidence interval	Negative percent agreement	95% Exact Confidence interval
Total	**99.7% (610/612)**	**98.8 – 99.9**	**98.7% (227/230)**	**96.2 – 99.7**

R : Reactive, NR : Nonreactive, BRD : Borderline

[a] : the Borderline result with MONOLISA™ Anti-HAV EIA was considered as false positive

[b] the specimen that was Borderline with the comparative assay and reactive with MONOLISA™ Anti-HAV EIA was considered as false positive with MONOLISA™ Anti-HAV EIA.

[c] the specimen that was Borderline with the comparative assay and nonreactive with MONOLISA™ Anti-HAV EIA was considered as false negative with MONOLISA™ Anti-HAV EIA.

[d] :the 2 borderline results with both MONOLISA™ Anti-HAV EIA and with the comparative assay were not included in the calculation of the negative agreement or the positive agreement.

Acute HAV Infection:

Among the retrospective samples, 84 were from subjects with a medical history and laboratory results indicative of acute Hepatitis A. The subjects included 56% male, 37% female; the gender was not available for 7%. The mean age was 21, and subjects ranged from 1 to 55 years. Among them 39 were pediatric subjects.

The results are presented in the following table:

Table 12: Comparison of Results for MONOLISA™ Anti-HAV EIA versus the comparative assay on Acute HAV infection in the adult and pediatric European Population (N= 84) :

	Comparative assay: Positive			Comparative assay: Borderline			Comparative assay: Negative			
	MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			Total
	R	BRD	NR	R	BRD	NR	R	BRD	NR	
Adults	45	0	0	0	0	0	0	0	0	45
Pediatrics	39	0	0	0	0	0	0	0	0	39
Total	**84**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**84**

R: Reactive, NR: Nonreactive, BRD : Borderline

The positive agreement was 100% (84/84) with a 95% exact confidence interval of 96.5% to 100%.

Performance of MONOLISA™ Anti-HAV EIA in pediatric subjects:

Sixty (60) pediatric samples were tested during the US and European clinical studies in addition to the 39 pediatric samples from acute HAV infection.
Among the US population, 23 had signs and symptoms of hepatitis and 2 were from the high risk group. In the European population, 3 belonged to the general hospitalized population, 22 had signs and symptoms of hepatitis, 2 were from the high risk group, 3 were healthcare workers, 5 had recovered from Hepatitis A infection. The results from these pediatric samples are summarized in the following table.

Table 13 : Comparison of Results for MONOLISA™ Anti-HAV EIA versus the comparative assay in the Pediatric European and US Population (N= 60)

Subject category	Comparative assay: Positive			Comparative assay: Borderline			Comparative assay: Negative			Total
	MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			
	R	BRD	NR	R	BRD	NR	R	BRD	NR	
European Pediatrics	16	0	0	0	0	0	0	0	19	35
US Pediatrics	13	0	0	0	0	0	0	1	11	25
Total	**29**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**30**	**60**

	Positive percent agreement	95% Exact Confidence interval	Negative percent agreement	95% Exact Confidence interval
Total	**100% (29/29)**	**90.2 - 100**	**96.8% (30/31)**	**83.3 – 99.9**

R: Reactive, NR: Nonreactive, BRD: Borderline

Including the combined US and European Sites, the positive percent agreement of the MONOLISA™ Anti-HAV EIA with the comparative anti-HAV assay was 99.5% (931/936) with a 95% exact confidence interval of 98.8% to 99.8%. The negative percent agreement of the MONOLISA™ Anti-HAV EIA with the comparative anti-HAV assay was 96.2% (378/393) with a 95% exact confidence interval of 93.8% to 97.9%.

Study On Vaccinated Subjects:

The HAV antibody response to vaccination was evaluated with 3 different vaccines that are currently licensed in the US: VAQTA® from Merck & Co, HAVRIX® 1440 from Glaxo SmithKline and TWINRIX® from Glaxo SmithKline.

For VAQTA® vaccine, 6 post-vaccination samples from US subjects were available.
For HAVRIX® vaccine, 10 matched sets of pre- and post-vaccination samples from European subjects and 8 post-vaccination samples from US subjects were available.
For TWINRIX® vaccine, 14 matched sets of pre-vaccination and post first dose samples from European individuals were available.

The following results were obtained:

Table 14: MONOLISA™ Anti-HAV EIA Results on Vaccinated Subjects versus the comparative assay - All testing sites

		Comparative assay: Positive			Comparative assay: Borderline			Comparative assay: Negative			Total
		MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti- HAV EIA			MONOLISA™ Anti-HAV EIA			
		R	BRD	NR	R	BRD	NR	R	BRD	NR	
VAQTA	Post-vaccination	6	0	0	0	0	0	0	0	0	6
HAVRIX	Pre-vaccination	0	0	0	0	0	0	0	0	10	10
	Post-vaccination	18	0	0	0	0	0	0	0	0	18
TWINRIX	Pre-vaccination	1	0	0	0	0	0	1*	0	12	14
	Post 1st injection	9	1	0	0	0	2	0	0	2	14

R : reactive, NR : Nonreactive , BRD : Borderline
* Result close to the cutoff value (CO/S=1.2)

In pre-vaccination samples, MONOLISA™ Anti-HAV EIA was in overall agreement with the comparative assay for 21/22 (95.5%) of samples tested.
For TWINRIX® vaccine on post first dose vaccination, MONOLISA™ Anti-HAV EIA demonstrated reactivity in 9/14 (64.3%) samples. The reference method demonstrated reactivity in 10/14 (71.4%) samples.
For HAVRIX® post-vaccination samples, MONOLISA™ Anti-HAV EIA demonstrated reactivity in 18/18 (100%) samples. The reference method demonstrated reactivity in 18/18 (100%) samples.
For VAQTA® post-vaccination samples, MONOLISA™ Anti-HAV EIA demonstrated reactivity in 6/6 (100%) samples. The reference method demonstrated reactivity in 6/6 (100%) samples.

Seroconversion Panels

Six commercially available HAV seroconversion panels were tested using MONOLISA™ Anti-HAV EIA and the FDA approved comparative assay to determine the sensitivity of the assay. The results are summarized in the following table:

Table 15: MONOLISA™Anti-HAV EIA Seroconversion Panels Results :

Panel ID	MONOLISA™ Anti-HAV EIA	Comparative assay	
	Post bleed day of first reactive result	Post bleed day of first reactive result	Difference in Days to Reactive result
07467A	0	0	0
60160K	0	0	0
HAV01	0	0	0
RP-004	0	6	- 6
RP-013	8	8	0
PHT902	16	16	0

The sensitivity of the MONOLISA™ Anti-HAV EIA was equivalent to or more sensitive than the comparative assay in the six seroconversion panels tested.

Cross Reactivity Study

The potential for cross reactivity to other disease states, or viruses was evaluated for the MONOLISA™ Anti-HAV EIA Assay and the comparative assay.

In addition, samples containing rheumatoid factors, auto-antibodies, anti-mouse antibodies were tested.

In total, 255 specimens (including both serum and plasma) from 16 groups of potential cross-reactivity were tested. FDA approved methods were used to confirm the disease state of each specimen.

The results are summarized in the following table.

BIO-RAD

Table 16: Potential cross reactivity study

Clinical Condition	Comparative assay Positive			Comparative assay BRD			Comparative assay Negative			
	MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			MONOLISA™ Anti-HAV EIA			Total
	R	BRD	NR	R	BRD	NR	R	BRD	NR	
Hepatitis C (HCV)	7	0	1	0	0	0	0	0	7	15
Hepatitis B (HBV) HBs Ag	9	0	0	0	0	0	0	0	6	15
Hepatitis B (HBV) anti HBc	10	0	0	0	0	0	3	1	1	15
Human Immunodeficiency Virus (HIV)	6	0	1	1	0	0	0	0	7	15
Epstein Barr Virus (EBV) IgG	1	0	0	1	0	0	0	0	13	15
Epstein Barr Virus (EBV) IgM	15	0	0	0	0	0	0	0	0	15
Cytomegalovirus (CMV) IgG	6	0	0	0	0	0	0	0	9	15
Cytomegalovirus (CMV) IgM	7	0	0	0	0	0	0	0	8	15
Rubella IgG	5	0	1	0	0	0	0	0	9	15
Toxoplasmosis IgG	10	0	0	0	0	0	0	0	5	15
Toxoplasmosis IgM	8	2	0	0	0	1	0	0	4	15
Mumps IgG	3	0	0	0	0	0	1	0	11	15
Varicella Zoster Virus(VZV) IgG	1	0	0	0	0	0	0	0	14	15
Varicella Zoster Virus(VZV) IgM	6	0	0	1	0	1	0	0	7	15
Anti Nuclear Antibody (ANA)	7	0	0	0	0	1	0	0	7	15
Human Anti Mouse Antibody (HAMA)	2	0	0	0	0	1	0	0	12	15
Rheumatoid Arthritis	12	0	0	0	0	0	0	0	3	15
Total	**115**	**2**	**3**	**3**	**0**	**4**	**4**	**1**	**123**	**255**

7 samples were discrepant: 4 reactive on MONOLISA™ Anti-HAV EIA, nonreactive on comparative assay and 3 were nonreactive on MONOLISA™ Anti-HAV EIA and reactive on comparative assay.

Precision Study

Within-Laboratory Precision Study :

A 21-member panel was tested: serum samples with the 6 corresponding plasma samples (EDTA K2, EDTA K3, Sodium Citrate, Sodium Heparin, Lithium heparin, ACD) at 3 different levels (1 negative, 1 negative near the cutoff, 1 low positive near the cutoff) were tested on 1 lot, in duplicate, in 2 different runs per day (am and pm), by the same operator for a period of 20 days. The data were analyzed following the CLSI guidance EP5A2. The mean ratio, the Standard Deviation (SD) and percent coefficient of variation (%CV) were calculated for each panel member.

The data summary is shown in the following tables.

Table 17: MONOLISA™ Anti-HAV EIA Precision Results by Panel Member Cutoff to Signal (CO/S)

Panel Member	N	Mean CO/S	Within run[1]		Between Run [2]		Between Day [3]		Total [4]	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Negative Control C0	40	0.282	NA	NA	0.02	6.4%	0.01	5.0%	0.02	8.1%
Positive Control C1	40	4.093	NA	NA	0.54	13.5%	0.00	0.0%	0.49	12.3%
Serum 1	80	0.395	0.02	4.1%	0.03	6.3%	0.01	1.9%	0.03	7.7%
EDTA K2 1	80	0.379	0.02	5.0%	0.03	6.8%	0.01	1.4%	0.03	8.6%
EDTA K3 1	80	0.376	0.01	3.4%	0.04	9.3%	0.00	0.0%	0.04	9.9%
Sodium Citrate 1	80	0.387	0.04	10.1%	0.01	3.3%	0.02	5.1%	0.05	11.8%
Sodium Heparin 1	80	0.363	0.01	3.4%	0.03	7.6%	0.00	0.0%	0.03	8.3%
Lithium Heparin 1	80	0.364	0.01	3.4%	0.03	7.0%	0.01	3.5%	0.03	8.5%
ACD 1	80	0.402	0.02	4.3%	0.04	10.4%	0.00	0.0%	0.05	11.3%
Serum 2	80	0.691	0.03	4.9%	0.06	9.6%	0.01	2.3%	0.06	11.0%
EDTA K2 2	80	0.657	0.02	3.2%	0.05	6.6%	0.01	1.8%	0.05	7.5%
EDTA K3 2	80	0.686	0.03	4.9%	0.06	8.2%	0.00	0.0%	0.07	9.5%
Sodium Citrate 2	80	0.636	0.03	3.7%	0.05	7.0%	0.03	4.8%	0.06	9.2%
Sodium Heparin 2	80	0.628	0.02	3.1%	0.04	6.0%	0.03	4.2%	0.06	7.9%
Lithium Heparin 2	80	0.685	0.05	6.6%	0.06	8.6%	0.00	0.0%	0.08	10.8%
ACD 2	80	0.746	0.04	5.6%	0.05	6.4%	0.03	4.7%	0.07	9.7%
Serum 3	80	1.506	0.06	4.2%	0.14	9.4%	0.00	0.4%	0.15	10.3%
EDTA K2 3	80	1.261	0.07	4.7%	0.11	7.0%	0.07	4.8%	0.15	9.7%
EDTA K3 3	80	1.257	0.04	2.4%	0.09	6.0%	0.05	3.6%	0.11	7.4%
Sodium Citrate 3	80	1.462	0.08	5.1%	0.13	8.7%	0.07	4.9%	0.17	11.2%
Sodium Heparin 3	80	1.380	0.11	7.5%	0.12	8.0%	0.05	3.4%	0.17	11.4%
Lithium Heparin 3	80	1.346	0.08	5.6%	0.11	7.1%	0.03	1.8%	0.14	9.2%
ACD 3	80	1.344	0.05	3.4%	0.08	5.6%	0.09	6.0%	0.13	8.9%

NA : Not Applicable

[1] Within Run: variability of the assay performance from replicate to replicate

[2]Between Run: variability of the assay performance from Run to Run

[3]Between Day: variability of the assay performance from Day to Day

[4]Total :total variability of the assay performance includes within run, between run and between day.

BIO-RAD

Reproducibility Study:

A 6 member panel consisting of diluted plasma specimens (negative and different levels of positive) was tested in triplicate, once a day for 3 days on 3 lots* of MONOLISA™ Anti-HAV EIA at 3 separate clinical trial sites. Each panel was coded with a different number on each day tested in order to blind the operator to the expected value of the sample.
**:3 different lots were used at the Bio-Rad site and 2 lots were used on each of the external sites.*

The data from all reagent lots and sites were combined to obtain Standard Deviation (SD) and percent coefficient of variation (CV) for within run, between day, between lot, between site and total variance. The data were analyzed according to the principles described in the Clinical Laboratory Standards Institute guidance EP5-A2, revised November 2004 and ISO/TR 22971:2005. The PROC GLM procedure in SAS® was used to estimate the variance components of the model. The model was y = site + lot (site) + day (lot site) + error.
The summaries are shown in the following tables.

Table 18: MONOLISA™ Anti-HAV EIA Reproducibility Results by Panel Member Cutoff to Signal (CO/S)

Test site	Panel Member	N	Mean	Within Run[1]		Between Day[2]		Between Lot[3]		Total[4]	
			CO/S	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Site #1	P1	18	0.33	0.01	3.03	0.09	28.1	0[5]	0	0.09	28.3
	P2	18	0.68	0.03	4.9	0.07	10.0	0[5]	0	0.07	11.1
	P3	18	1.02	0.05	5.0	0.05	5.2	0[5]	4.1	0.08	8.3
	P4	18	1.98	0.09	4.7	0.32	16.0	0[5]	0	0.33	16.7
	P5	18	2.48	0.18	7.4	0.36	14.8	0[5]	0	0.41	16.5
	P6	18	3.66	0.23	6.2	0.20	5.5	0[5]	0	0.3	8.3
Site#2	P1	18	0.35	0.01	1.6	0.02	4.7	0.01	1.2	0.02	5.1
	P2	18	0.92	0.03	3.0	0.07	8.0	0[5]	0	0.08	8.5
	P3	18	1.28	0.04	3.5	0.00	0.0	0.01	0.62	0.05	3.6
	P4	18	2.32	0.08	3.6	0.20	8.5	0.02	0.95	0.21	9.3
	P5	18	3.10	0.13	4.1	0.20	6.4	0[5]	0	0.23	7.5
	P6	18	4.16	0.13	3.2	0.36	8.7	0[5]	0	0.39	9.3
Site #3	P1	27	0.36	0.01	4.0	0.02	5.4	0.02	6.6	0.03	9.4
	P2	27	0.81	0.03	3.4	0.03	3.9	0.06	7.2	0.07	8.8
	P3	27	1.27	0.08	6.6	0.04	3.6	0.14	11.2	0.17	13.5
	P4	27	2.16	0.11	5.0	0.05	2.2	0.34	15.7	0.36	16.6
	P5	27	3.09	0.11	3.7	0.15	4.9	0.49	15.7	0.52	16.9
	P6	27	4.47	0.11	2.5	0.33	7.3	1.01	22.5	1.06	23.8

[1] Within Run: variability of the assay performance from replicate to replicate
[2]Between Day: variability of the assay performance from Day to Day
[3]Between Lot: variability of the assay performance from Lot to Lot
[4]Total : total variability of the assay performance includes within run, between day and between lot.
[5] Negative variances were rounded to zero, per statistical convention.

BIO-RAD

Table 19: MONOLISA™ Anti-HAV Reproducibility Summary by Panel Member Cutoff to Signal (CO/S)

Panel Member	N	Mean	Within Run[1]		Between Day[2]		Between Lot[3]		Between Site[5]		Total[4]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
P1	63	0.35	0.01	3.2	0.05	14.8	0[5]	0	0.01	2.9	0.05	15.5
P2	63	0.80	0.03	3.7	0.06	7.12	0.03	3.7	0.11	13.4	0.13	16.0
P3	63	1.20	0.07	5.5	0.04	3.3	0.10	8.6	0.12	10.3	0.18	14.9
P4	63	2.15	0.10	4.5	0.20	9.5	0.22	10.0	0.00	0.0	0.31	14.5
P5	63	2.92	0.14	4.8	0.24	8.3	0.32	11.0	0.25	8.7	0.50	17.0
P6	63	4.15	0.16	3.8	0.31	7.4	0.70	16.9	0[5]	0	0.78	18.9

[1] Within Run: variability of the assay performance from replicate to replicate
[2]Between Day: variability of the assay performance from Day to Day
[3]Between Lot: variability of the assay performance from Lot to Lot
[5]Between site: variability of the assay performance from Site to Site
[4]Total : total variability of the assay performance includes within run, between day between lot and between site.
[5] Negative variances were rounded to zero, per statistical convention.

Reproducibility study on Negative and Positive Controls:

The negative and positive controls were tested in triplicate, once a day by 3 different operators for 3 days. The data were analyzed according to the principles described in the Clinical Laboratory Standards Institute guidance EP5-A2, revised November 2004 and ISO/TR 22971:2005.

Table 20: MONOLISA™ Anti-HAV EIA Control Reproducibility summary by Operator (CO/S)

Samples	N	Mean	Within Run[1]		Between Day[2]		Between Operator[3]		Total[4]	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	27	0.30	0.01	2.6	0.02	8.3	0[5]	0	0.03	8.7
Positive Control	27	4.74	0.16	3.5	0.48	10.1	0.07	1.5	0.51	10.8

[1] Within Run: variability of the assay performance from replicate to replicate
[2]Between Day: variability of the assay performance from Day to Day
[3] Between operator: variability of the assay performance from Operator to Operator
[4]Total :total variability of the assay performance includes within run, between day and between Operator.
[5] Negative variances were rounded to zero, per statistical convention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Manuela Kaul
RA-Manager
Bio-Rad France
3, Boulevard Raymond Poincaré
92430 Marnes-la-Coquette, France

MAY - 3 2007

Re: k063318
Trade/Device Name: MONOLISA™ Anti-HAV EIA
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A Virus (HAV) Serological Reagents
Regulatory Class: Class II
Product Code: LOL
Dated: March 21, 2007
Received: April 3, 2007

Dear Ms. Kaul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Devices
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number : K 063318

Device Name: MONOLISA™ Anti-HAV EIA

Indications for Use:

The MONOLISA™ Anti-HAV EIA is an in vitro enzyme immunoassay kit intended for use in the qualitative detection of total antibodies (IgG and IgM) to Hepatitis A Virus (anti-HAV) in human (adult and pediatric) serum or plasma (EDTA, Heparin, Citrate, ACD). This kit can be used as an aid in the diagnosis of acute or past Hepatitis A Virus (HAV) infection or as an aid in the identification of HAV-susceptible individuals for vaccination. However, any diagnosis should take into consideration the patient's clinical history and symptoms, as well as serological data.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, and cord blood or neonatal specimens.

WARNING : This assay is not intended for screening blood or solid or soft tissue donors.

Prescription Use: __X__ AND/OR Over-The-Counter Use: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k063318