DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 8, 2017

IMMCO Diagnostics, Inc.
Kevin Lawson
VP Regulatory Affairs
9870 Hollingson Road
Clarence, New York 14031

Re: K163133
Trade/Device Name: ImmuLisa Enhanced AMA IgG Antibody ELISA
ImmuLisa Enhanced AMA IgA/IgG/IgM Antibody ELISA
Regulation Number: 21 CFR 866.5090
Regulation Name: Antimitochondrial antibody immunological test system
Regulatory Class: Class II
Product Code: DBM
Dated: July 1, 2017
Received: July 5, 2017

Dear Mr. Lawson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163133

Device Name
ImmuLisa™ Enhanced Mitochondria Antibody (AMA) IgA/IgG/IgM ELISA

Indications for Use *(Describe)*
An enzyme linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of anti-mitochondria antibodies (AMA) in human serum to aid in the diagnosis of primary biliary cirrhosis (PBC) in conjunction with other laboratory tests and clinical findings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163133

Device Name
ImmuLisa™ Enhanced Mitochondria Antibody (AMA) IgG ELISA

Indications for Use *(Describe)*
An enzyme linked immunoassay (ELISA) for the qualitative or semi-quantitative detection of anti-mitochondria IgG antibodies in human serum to aid in the diagnosis of primary biliary cirrhosis (PBC) in conjunction with other laboratory tests and clinical findings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter: Immco Diagnostics, Inc.
Address: 60 Pineview Dr., Buffalo, NY 14228
Phone Number: 716-691-0091 ext. 110
Contact: Kevin Lawson

Summary Prepared: 6-27-2017

Device Name: ImmuLisa Enhanced™ Anti-Mitochondria IgG Antibody (AMA) ELISA
Common Name: Anti-Mitochondria IgG Antibody (AMA) ELISA
Product Code: Antimitochondrial antibody, indirect immunofluorescent, antigen, control [DBM]
Substantially Equivalent to: INOVA QUANTA Lite™ M2 EP (MIT3)

General Description: Primary biliary cirrhosis (PBC) is a disease of the liver characterized by inflammatory obliteration of the intrahepatic bile ducts. PBC is characterized by the presence of anti-mitochondria antibodies (AMA). AMA detected by indirect immunofluorescence (IF) occur in approximately 90% of patients with PBC and in 2-5% of patients with autoimmune hepatitis as well as in certain other disorders such as syphilis and drug induced hepatitis. As many as nine different staining reactions have been described by indirect IF, but only one, the M2 reaction is specific for PBC. Inability to easily distinguish different AMA reactions compromises the utility of indirect IF test methods for diagnosing PBC. Biochemical and immunochemical studies have identified the E2 component of pyruvate dehydrogenase complex (PDC-E2) to be the immunodominant PBC specific mitochondria antigen. Other significant autoantibody markers for PBC are the E2 subunit of the 2-oxoglutarate dehydrogenase complex (OGDC-E2) and the E2 subunit of the branched-chain 2-oxoacid dehydrogenase complex (BCOADC-E2). Anti-M2 mitochondrial antibodies are typically detected by IgG; however, literature reports a number of cases with elevated levels of IgA and/or IgM isotype antibodies rather than IgG. A combination of individual anti-mitochondrial antigens are coated in one well to facilitate immunoassay sensitivity and specificity for the detection of AMA associated with PBC.
This test is performed as a solid phase immunoassay. Microwells are coated with recombinant Mitochondrial antigen. Controls, calibrators and patient sera are incubated in the antigen coated wells to allow specific antibodies present in the serum to bind to the Mitochondria antigen. Bound antibodies are detected by adding an enzyme labeled anti-human IgG or IgA/IgG/IgM conjugate. Specific enzyme substrate (TMB) is then added and the presence of antibodies is detected by a color change that is read by a spectrophotometer at 450 nm. Results are expressed in ELISA units per milliliter (EU/ml) and reported as positive or negative.

Intended Use: An enzyme linked immunoassay (ELISA) for the qualitative or semi-quantitative detection of anti-mitochondria IgG antibodies in human serum to aid in the diagnosis of primary biliary cirrhosis (PBC) in conjunction with other laboratory tests and clinical findings.

Similarities and Differences: Both kits use mitochondrial antigen coated on 96 well plates to detect mitochondria IgG antibodies with HRP anti-human conjugate and TMB substrate. Both kits test human serum. The IMMCO kit utilizes a 5 point calibrator curve for semi-quantitative results while the predicate kit utilizes a single calibrator. The Immco semi-quantitative results are reported in EU/ml while the Inova kit results are expressed in units. Both kits use a borderline/indeterminate range of 20-25EU/ml.

Non-clinical Tests:

Method Comparison: Both kits were tested with well-characterized primary biliary cirrhosis subjects and disease controls.

ImmuLisa™ AMA IgG ELISAs vs. other AMA IgG ELISA:

		Other AMA IgG ELISA			
		Pos	Indeterminate	Neg	Tot
Immco AMA IgG ELISA	Pos	98	11	14	123
	Indeterminate	3	0	1	4
	Neg	6	5	296	307
	Total	107	16	311	434

Borderline considered positive			
Positive % Agreement	91.1%	112/123	(95%CI 84.2 - 95.2)
Neagtive % Agreement	95.2%	296/311	(95%CI 92.0 - 97.2)
Overall % Agreement	94.0%	408/434	(95%CI 91.2 - 96.0)
Borderline considered negative			
Positive % Agreement	91.6%	98/107	(95%CI 84.2 - 95.8)
Neagtive % Agreement	92.4%	302/327	(95%CI 88.8 - 94.9)
Overall % Agreement	92.2%	400/434	(95%CI 89.1 - 94.4)
Borderline excluded			
Positive % Agreement	94.2%	98/104	(95%CI 87.4 - 97.6)
Neagtive % Agreement	95.5%	296/310	(95%CI 92.4 - 97.4)
Overall % Agreement	95.2%	394/414	(95%CI 92.5 - 97.0)

Cross Reactivity: Potentially cross-reactive specimens from individuals with other autoimmune, infectious or related disorders were tested for AMA antibodies using the ImmuLisa™ AMA IgG ELISA.

Condition	n	n Pos	% Pos
Autoimmune hepatitis (AIH)	38	1	2.6%
Primary sclerosing cholangitis	20	0	0.0%
Antiphospholipid syndrome	48	0	0.0%
Celiac disease	99	0	0.0%
Crohn's disease	25	0	0.0%
Mixed connective tissue disoder	16	0	0.0%
Myositis	26	0	0.0%
Rheumatoid arthritis	106	1	0.9%
Sjogren's syndrome	54	0	0.0%
Systemic lupus erythematosus	154	0	0.0%
Systemic sclerosis	26	0	0.0%
Ulcerative colitis	25	0	0.0%
CMV	20	1	5.0%
HepC	74	0	0.0%
HSV 1	20	0	0.0%
HSV 2	20	1	5.0%
Lyme disease	16	0	0.0%
Mononucleosus	20	0	0.0%
Rubella	26	2	7.7%
Syphilis	23	2	8.7%
Toxoplasmosis	20	1	5.0%
Alcoholic liver disease	12	0	0.0%
Hepatocellular carcinoma	10	0	0.0%

Precision

Precision was tested with positive specimens selected throughout the range of the assay. Seven patients were run in duplicate, twice per day for 20 days (n=80 replicates per sample). Assays were run by two operators on two different sets of equipment.

		Total Imprecision		Within Run (Repeatability)		Between Day		Inter-operator / equipment	
Sample	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	13.8	1.4	9.8	0.8	5.8	0.6	4.2	1.1	7.9
2	16.0	1.6	10.0	0.7	4.1	1.2	7.7	1.0	6.0
3	19.7	1.5	7.6	0.7	3.7	0.4	2.0	1.3	6.7
4	23.6	1.3	5.5	0.7	3.1	0.6	2.3	1.1	4.5
5	78.1	7.2	9.2	3.2	4.1	1.9	2.5	6.4	8.2
6	111.2	9.0	8.1	4.5	4.0	1.1	6.9	7.8	7.0
7	159.9	10.0	6.3	4.9	3.0	2.7	1.7	8.8	5.5

Reproducibility
80 replicates of samples in the low negative range, near the cutoff, in the moderate positive range, high positive range and approximately +/- 20% of the assay cutoffs for each AMA isotype were performed to determine qualitative reproducibility. Assay results for low negative, +20%, moderate positive and high positive specimens produced 100% qualitative agreement. -20% specimens produced 98% qualitative agreement. Approximate cutoff specimens produced 63% qualitative agreement.

Limit of Detection
Based on 60 replicates of the blank and 10 replicates each of 6 low-level (NHS) samples the limits of detection (LoD) for AMA antibodies were determined to be 3.3 EU/ml.

Linearity and Recovery
Studies were performed using equidistant dilution series of positive samples with values throughout the calibrator range to determine linear range of the assay. The linear range of the assay was determined to be 3.3 to 160 EU/ml. Results are summarized below.

Test Range (EU/ml)	Slope (95% CI)	Y-intercept (95% CI)	R2	% Recovery (Obtnd/Expctd)
3.4 to 57.4	0.99 (.94 to 1.04)	0.94 (-0.858 to 2.74)	0.997	93% to 102%
6.0 to 81.0	1.00 (0.95 to 1.05)	-0.89 (-3.28 to 1.49)	0.9978	100% to 109%
54.9 to 162.4	0.96 (0.89 to 1.03)	3.15 (-5.04 to 11.34)	0.995	95% to 106%

To assess hook effect, dilutions of high positive specimens with results above the 160 EU/ml measuring range were tested. Hook effect was not demonstrated in dilution samples as high as ~15,356.8 EU/ml within OD range of the microplate reader (~3.5OD).

Interference
Interference was studied by mixing sera with known AMA levels for each isotype with potentially interfering serum substances and studying deviation from expected results. No significant interference was demonstrated for the following substances at the levels indicated: Hemoglobin (2 g/L), Bilirubin (342 µmol/L), Rheumatoid Factor (100 EU/ml), Triglycerides (37 mmol/L).

Clinical Study: Sets of clinical samples were tested on the IMMCO Mitochondria ELISA. This included 193 primary biliary cirrhosis and 898 autoimmune and infectious disease controls.

Primary biliary cirrhosis Clinical Sensitivity: 85.5% (95%CI 79.5 – 90.0)
Primary biliary cirrhosis Clinical Specificity: 99.0% (95%CI 98.0 - 99.5)

Indeterminate samples for these studies were considered positive. NHS were excluded in sensitivity/specificity calculations.

Kevin J. Lawson
VP Regulatory Affairs

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510(k) Summary

Submitter: Immco Diagnostics, Inc.
Address: 60 Pineview Dr., Buffalo, NY 14228
Phone Number: 716-691-0091 ext. 110
Contact: Kevin Lawson

Summary Prepared: 6-27-2017

Device Name: ImmuLisa Enhanced™ Anti-Mitochondria IgA/IgG/IgM Antibody (AMA) ELISA
Common Name: Anti-Mitochondria IgA/IgG/IgM Antibody (AMA) ELISA
Product Code: Antimitochondrial antibody, indirect immunofluorescent, antigen, control [DBM]
Substantially Equivalent to: Trinity Captia™ Mitochondria IgA/IgG/IgM Screen

General Description: Primary biliary cirrhosis (PBC) is a disease of the liver characterized by inflammatory obliteration of the intrahepatic bile ducts. PBC is characterized by the presence of anti-mitochondria antibodies (AMA). AMA detected by indirect immunofluorescence (IF) occur in approximately 90% of patients with PBC and in 2-5% of patients with autoimmune hepatitis as well as in certain other disorders such as syphilis and drug induced hepatitis. As many as nine different staining reactions have been described by indirect IF, but only one, the M2 reaction is specific for PBC. Inability to easily distinguish different AMA reactions compromises the utility of indirect IF test methods for diagnosing PBC. Biochemical and immunochemical studies have identified the E2 component of pyruvate dehydrogenase complex (PDC-E2) to be the immunodominant PBC specific mitochondria antigen. Other significant autoantibody markers for PBC are the E2 subunit of the 2-oxoglutarate dehydrogenase complex (OGDC-E2) and the E2 subunit of the branched-chain 2-oxoacid dehydrogenase complex (BCOADC-E2). Anti-M2 mitochondrial antibodies are typically detected by IgG; however, literature reports a number of cases with elevated levels of IgA and/or IgM isotype antibodies rather than IgG. A combination of individual anti-mitochondrial antigens are coated in one well to facilitate immunoassay sensitivity and specificity for the detection of AMA associated with PBC.
This test is performed as a solid phase immunoassay. Microwells are coated with recombinant mitochondrial antigen. Controls, calibrators and patient sera are incubated in the antigen coated wells to allow specific antibodies present in the serum to bind to the Mitochondria antigen. Bound antibodies are detected by adding an enzyme labeled anti-human IgG or IgA/IgG/IgM conjugate. Specific enzyme substrate (TMB) is then added and the presence of antibodies is detected by a color change that is read by a spectrophotometer at 450 nm. Results are expressed in ELISA units per milliliter (EU/ml) and reported as positive or negative.

Intended Use: An enzyme linked immunosorbent assay (ELISA) for the qualitative or semi-quantitative detection of anti-mitochondria antibodies (AMA) in human serum to aid in the diagnosis of primary biliary cirrhosis (PBC) in conjunction with other laboratory tests and clinical findings.

Similarities and Differences: Both kits use mitochondrial antigen coated on 96 well plates to detect mitochondria IgA/IgG/IgM antibodies with HRP anti-human conjugate and TMB substrate. Both kits test human serum. The IMMCO kit utilizes a 5 point calibrator curve for semi-quantitative results while the predicate kit utilizes a single calibrator. The Immco semi-quantitative results are reported in EU/ml while the Trinity Captia kit results are expressed as a ratio. The Immco kit uses a borderline/indeterminate range of 20-25EU/ml while the Trinity Captia kit uses a ratio between sample result and calibrator of 0.9 to 1.1 for the borderline/indeterminate range.

Non-clinical Tests:

Method Comparison: Both kits were tested with well-characterized primary biliary cirrhosis subjects and disease controls.

		Other AMA Screen ELISA			
		Pos	Indeterminate	Neg	Tot
Immco	Pos	91	22	18	131
AMA IgA/G/M	Indeterminate	4	5	5	14
ELISA	Neg	3	2	303	308
	Total	98	29	326	453

immco DIAGNOSTICS
A Trinity Biotech Company

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Borderline considered positive			
Positive % Agreement	96.1%	122/127	(95%CI 90.6 -98.5)
Neagtive % Agreement	92.9%	303/326	(95%CI 89.5 - 95.4)
Overall % Agreement	93.8%	425/453	(95%CI 91.1 - 95.8)
Borderline considered negative			
Positive % Agreement	92.9%	91/98	(95%CI 85.3 - 96.8)
Neagtive % Agreement	88.7%	315/355	(95%CI 84.9 - 91.7)
Overall % Agreement	89.6%	406/453	(95%CI 86.4 - 92.2)
Borderline excluded			
Positive % Agreement	96.8%	91/94	(95%CI 90.3 - 99.2)
Neagtive % Agreement	94.4%	303/321	(95%CI 91.1 - 96.5)
Overall % Agreement	94.9%	394/415	(95%CI 92.3 - 96.8)

Cross Reactivity: Potentially cross-reactive specimens from individuals with other autoimmune, infectious or related disorders were tested for AMA antibodies using the ImmuLisa™ AMA IgA/IgG/IgM ELISA.

Condition	n	n Pos	% Pos
Autoimmune hepatitis (AIH)	38	4	10.5%
Primary sclerosing cholangitis	20	0	0.0%
Antiphospholipid syndrome	48	0	0.0%
Celiac disease	99	0	0.0%
Crohn's disease	25	0	0.0%
Mixed connective tissue disoder	16	0	0.0%
Myositis	26	0	0.0%
Rheumatoid arthritis	106	0	0.0%
Sjogren's syndrome	54	0	0.0%
Systemic lupus erythematosus	154	0	0.0%
Systemic sclerosis	26	1	3.8%
Ulcerative colitis	25	0	0.0%
CMV	20	1	5.0%
HepC	74	0	0.0%
HSV 1	20	3	15.0%
HSV 2	20	0	0.0%
Lyme disease	16	0	0.0%
Mononucleosus	20	3	15.0%
Rubella	26	0	0.0%
Syphilis	23	2	8.7%
Toxoplasmosis	20	0	0.0%
Alcoholic liver disease	12	1	8.3%
Hepatocellular carcinoma	10	0	0.0%

Precision

Precision was tested with positive specimens selected throughout the range of the assay. Seven patients were run in duplicate, twice per day for 20 days (n=80 replicates per sample). Assays were run by two operators on two different sets of equipment.

		Total Imprecision		Within Run (Repeatability)		Between Day		Inter-operator / equipment	
Sample	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	11.2	0.7	6.6	0.3	2.2	0.3	2.2	0.7	5.8
2	15.5	0.6	4.0	0.2	1.2	0.3	2.0	0.5	3.2
3	20.3	1.1	5.6	0.3	1.4	0.9	4.4	0.7	3.2
4	24.5	1.5	6.1	0.5	1.8	0.7	3.0	1.2	5.0
5	51.6	2.0	4.0	0.5	1.1	0.2	0.3	2.0	3.8
6	104.7	4.4	4.2	1.4	1.4	2.3	2.2	4.2	4.0
7	145.3	5.0	3.4	1.4	1.0	0.1	0.1	4.8	3.3

Reproducibility

80 replicates of samples in the low negative range, near the cutoff, in the moderate positive range, high positive range and approximately +/- 20% of the assay cutoffs for each AMA isotype were performed to determine qualitative reproducibility. Assay results for low negative, -20%, moderate positive and high positive specimens produced 100% qualitative agreement. +20% specimens produced 99% qualitative agreement. Approximate cutoff specimens produced 58% qualitative agreement.

Limit of Detection

Based on 60 replicates of the blank and 10 replicates each of 6 low-level (NHS) samples, the limit of detection (LoD) for AMA antibodies was determined to be 3.3 EU/ml.

Linearity and Recovery

Studies were performed using equidistant dilution series of positive samples with values throughout the calibrator range to determine linear range of the assay. The linear range of the assay was determined to be 3.3 to 160 EU/ml. Results are summarized below.

Test Range (EU/ml)	Slope (95% CI)	Y-intercept (95% CI)	R2	% Recovery (Obtnd/Expctd)
5.9 to 31.9	1.01 (.95 to 1.07)	0.39 (-0.89 to 1.67)	0.997	95% to 98%
28.9 to 83.4	1.08 (0.92 to 1.23)	-5.94 (-15.48 to 3.59)	0.979	96% to 113%
46.6 to 166.5	0.93 (0.83 to 1.03)	5.68 (-5.48 to 16.84)	0.989	95% to 108%

To assess hook effect, dilutions of high positive specimens with results above the 160 EU/ml measuring range were tested. Hook effect was not demonstrated in dilution samples as high as ~17,915.7 EU/ml within OD range of the microplate reader (~3.5OD).

Interference

Interference was studied by mixing sera with known AMA levels with potentially interfering serum substances and studying deviation from expected results. No significant interference was demonstrated for the following substances at the levels indicated: Hemoglobin (2 g/L), Bilirubin (342 µmol/L), Rheumatoid Factor (100 EU/ml), Triglycerides (37 mmol/L), and Cholesterol (13 mmol/L).

Clinical Study: Sets of clinical samples were tested on the IMMCO Mitochondria ELISA. This included 193 primary biliary cirrhosis and 898 autoimmune and infectious disease controls.

Primary biliary cirrhosis Clinical Sensitivity: 87.0% (95%CI 81.3 - 91.3)

Primary biliary cirrhosis Clinical Specificity: 98.5% (95%CI 97.2 - 99.0)

Indeterminate samples for these studies were considered positive. NHS were excluded in sensitivity/specificity calculations.

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VP Regulatory Affairs

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