

ALL HBV Combo Rapid Test Cassette

(Serum/Plasma)

REF IHB-355 English

A rapid test for the qualitative detection of Hepatitis B Surface Antigen (HBsAg), Hepatitis B Surface Antibody (HBsAb), Hepatitis B Envelope Antigen (HBeAg), Hepatitis B Envelope Antibody (HBeAb), and Hepatitis Core Antibody (HBcAb) in serum or plasma.

INTENDED USE

The HBV Combo Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma.

SUMMARY

Chronic hepatitis B is a serious, debilitating illness that can cause cirrhosis of the liver, liver cancer and death. Chronic hepatitis B is the main cause of liver cancer and the tenth leading cause of death worldwide, with 400,000,000 people infected with the virus. Every year, one million people worldwide are expected to die from this infection. Most people fight off the infection themselves, but approximately 5-10 percent of those infected with the virus become carriers, and an additional 5-10 percent of those infected each year will progress to chronic liver disease, cirrhosis and possibly liver cancer. The HBV Combo Rapid Test Cassette (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma without the use of a laboratory instrument.

PRINCIPLE

The HBsAg and HBeAg tests are qualitative, two-site sandwich immunoassays for the detection of HBsAg or HBeAg in serum or plasma. The membrane is pre-coated with anti-HBsAg or anti-HBeAg antibodies on the test line region of the strip. During testing, the serum or plasma specimen reacts with the particle coated with anti-HBsAg or anti-HBeAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action and reacts with anti-HBsAg or anti-HBeAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBsAg

Hepatitis B surface Antibody (HBsAb) is also known as anti-Hepatitis B surface Antigen (anti-HBs). This test is a qualitative, lateral flow immunoassay for the detection of HBsAb in serum or plasma. The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillary action and reacts with HBsAg on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

HBeAg and HBeAb

Hepatitis B envelope Antibody (HBeAb) is also known as anti-Hepatitis B envelope Antigen (anti-HBe). Hepatitis B core Antibody (HBcAb) is also known as anti-Hepatitis B core Antigen (anti-HBc). These tests are immunoassays based on the principle of competitive binding. During testing, the mixture migrates upward on the membrane chromatographically by capillary action. The membrane is pre-coated with HBeAg or HBcAg on the test line region of the strip. During testing, anti-HBe antibody or anti-HBc antibody, if present in the specimen, will compete with particle coated anti-HBe antibody or anti-HBc antibody for limited amount of HBeAg or HBcAg on the membrane, and no line will form in the test line region, indicating a positive result. A visible colored line will form in the test line region if there is no anti-HBe antibody or anti-HBc antibody in the specimen because all the antibody coated particles will be captured by the antigen coated in the test line region.

To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains anti-HBsAg particles, HBsAg particles, anti-HBeAg particles, HBcAg particles, respectively, and anti-HBsAg, HBsAg, anti-HBeAg, Anti-HBcAg coated on the membrane respectively.

PRECAUTIONS

- Please read all the information in this package insert before performing the test.
- For professional in vitro diagnostic use only. Do not use after the expiration date.
 - Do not eat, drink or smoke in the area where the specimens or kits are used.
 - Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
 - Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
 - Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

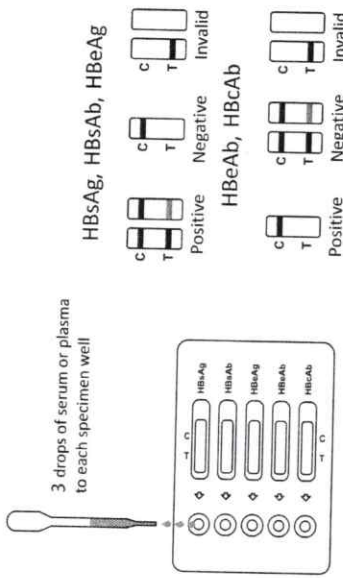
- The HBV Combo Rapid Test Cassette can be performed using either serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

- Test cassettes
- Materials provided
 - Droppers
- Materials required but not provided
 - Package insert
 - Timer
- Specimen collection containers Centrifuge

DIRECTIONS FOR USE

- Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
- Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75 µl) to each sample well of the test cassette respectively, then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
- Wait for the red line to appear. The result should be read at 15 minutes. Do not interpret the results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

Warning: Do not interpret all 5 tests with the same criterion. Carefully follow the directions below

HBsAg, HBsAb, HBeAg

POSITIVE: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of HBsAg, HBsAb, HBeAg present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

HBeAb, HBcAb

NEGATIVE: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T).

NOTE: The intensity of the color in the test line region (T) may vary. But it should be considered negative whenever there is even a faint pink line.

POSITIVE: One colored line appears in the control region (C). No apparent colored line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The HBV Combo Rapid Test Cassette is for professional in vitro diagnostic use only. The test should be used for the detection of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in serum or plasma specimen. Neither the quantitative value nor the rate of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb concentration can be determined by this qualitative test.
- The HBV Combo Rapid Test Cassette will only indicate the presence of HBsAg, HBsAb, HBeAg, HBeAb and HBcAb in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis B viral infection.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The HBV Combo Rapid Test Cassette (Serum/Plasma) was compared with leading commercial EIA/RIA HBsAg, HBsAb, HBeAg, HBeAb, HBcAb tests, the results show that the HBV Combo Rapid Test Cassette (Serum/Plasma) has a high sensitivity and specificity.

Method		HBsAg		HBsAb		HBeAg		HBeAb		HBcAb		Total Results	
HBsAg Rapid Test Cassette (Serum/Plasma)	Results	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
		241	2	241	2	241	2	241	2	241	2	241	2
Total Results		243	359	243	359	243	359	243	359	243	359	243	359
Relative Sensitivity: >99.9% (95%CI*: 98.8%-100%)		241	361	241	361	241	361	241	361	241	361	241	361
Relative Specificity: 99.4% (95%CI*: 98.0%-100%)		0	359	0	359	0	359	0	359	0	359	0	359
Accuracy: 99.7% (95%CI*: 98.8%-100%)		241	361	241	361	241	361	241	361	241	361	241	361

*Confidence Intervals

HBsAg

Method	Results	Positive	Negative	Total Results
HBsAg Rapid Test Cassette (Serum/Plasma)	Positive	194	9	203
	Negative	7	391	398
Total Results		201	400	601
Relative Sensitivity: 96.5% (95%CI*: 93.0%-98.6%)		201	400	601
Relative Specificity: 97.8% (95%CI*: 95.8%-99.0%)		201	400	601
Accuracy: 97.3% (95%CI*: 95.7%-98.5%)		201	400	601

*Confidence Intervals

HBsAb

Method	Results	Positive	Negative	Total Results
HBsAb Rapid Test Cassette (Serum/Plasma)	Positive	154	9	163
	Negative	6	429	435
Total Results		160	438	598
Relative Sensitivity: 96.3% (95%CI*: 92.1%-98.6%)		160	438	598
Relative Specificity: 97.9% (95%CI*: 96.1%-99.1%)		160	438	598
Accuracy: 97.5% (95%CI*: 95.9%-98.6%)		160	438	598

*Confidence Intervals

HBeAg

Method	Results	Positive	Negative	Total Results
HBeAg Rapid Test Cassette (Serum/Plasma)	Positive	146	7	153
	Negative	4	329	333
Total Results		150	336	486
Relative Sensitivity: 97.3% (95%CI*: 93.3%-99.3%)		150	336	486
Relative Specificity: 97.9% (95%CI*: 95.8%-99.2%)		150	336	486
Accuracy: 97.7% (95%CI*: 96.0%-98.9%)		150	336	486

*Confidence Intervals

HBeAb

Method	Results	Positive	Negative	Total Results
HBeAb Rapid Test Cassette (Serum/Plasma)	Positive	358	4	362
	Negative	8	167	175
Total Results		366	171	537
Relative Sensitivity: 97.8% (95%CI*: 95.7%-99.1%)		366	171	537
Relative Specificity: 97.7% (95%CI*: 94.1%-99.4%)		366	171	537
Accuracy: 97.8% (95%CI*: 96.0%-98.8%)		366	171	537

*Confidence Intervals

HBcAb

Method	Results	Positive	Negative	Total Results
HBcAb Rapid Test Cassette (Serum/Plasma)	Positive	358	4	362
	Negative	8	167	175
Total Results		366	171	537
Relative Sensitivity: 97.8% (95%CI*: 95.7%-99.1%)		366	171	537
Relative Specificity: 97.7% (95%CI*: 94.1%-99.4%)		366	171	537
Accuracy: 97.8% (95%CI*: 96.0%-98.8%)		366	171	537

Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive, high positive of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb. The negative and positive values were correctly identified 99% of the time.

Inter-Assay Precision

Between-run precision has been determined by using the same three specimens of negative, low positive, high positive of HBsAg, HBsAb, HBeAg, HBeAb, HBcAb in 15 independent assays. Three different lots of the HBV Combo Rapid Test Cassette (Serum/Plasma) has been tested over a 10 days period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity

The HBV Combo Rapid Test Cassette (Serum/Plasma) has been tested by HIV, Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis D, Hepatitis E, Hepatitis F, Hepatitis G, Hepatitis H, Hepatitis I, Hepatitis J, Hepatitis K, Hepatitis L, Hepatitis M, Hepatitis N, Hepatitis O, Hepatitis P, Hepatitis Q, Hepatitis R, Hepatitis S, Hepatitis T, Hepatitis U, Hepatitis V, Hepatitis W, Hepatitis X, Hepatitis Y, Hepatitis Z, Hepatitis AA, Hepatitis AB, Hepatitis AC, Hepatitis AD, Hepatitis AE, Hepatitis AF, Hepatitis AG, Hepatitis AH, Hepatitis AI, Hepatitis AJ, Hepatitis AK, Hepatitis AL, Hepatitis AM, Hepatitis AN, Hepatitis AO, Hepatitis AP, Hepatitis AQ, Hepatitis AR, Hepatitis AS, Hepatitis AT, Hepatitis AU, Hepatitis AV, Hepatitis AW, Hepatitis AX, Hepatitis AY, Hepatitis AZ, Hepatitis BA, Hepatitis BB, Hepatitis BC, Hepatitis BD, Hepatitis BE, Hepatitis BF, Hepatitis BG, Hepatitis BH, Hepatitis BI, Hepatitis BJ, Hepatitis BK, Hepatitis BL, Hepatitis BM, Hepatitis BN, Hepatitis BO, Hepatitis BP, 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Hepatitis EJ, Hepatitis EK, Hepatitis EL, Hepatitis EM, Hepatitis EN, Hepatitis EO, Hepatitis EP, Hepatitis EQ, Hepatitis ER, Hepatitis ES, Hepatitis ET, Hepatitis EU, Hepatitis EV, Hepatitis EW, Hepatitis EX, Hepatitis EY, Hepatitis EZ, Hepatitis FA, Hepatitis FB, Hepatitis FC, Hepatitis FD, Hepatitis FE, Hepatitis FF, Hepatitis FG, Hepatitis FH, Hepatitis FI, Hepatitis FJ, Hepatitis FK, Hepatitis FL, Hepatitis FM, Hepatitis FN, Hepatitis FO, Hepatitis FP, Hepatitis FQ, Hepatitis FR, Hepatitis FS, Hepatitis FT, Hepatitis FU, Hepatitis FV, Hepatitis FW, Hepatitis FX, Hepatitis FY, Hepatitis FZ, Hepatitis GA, Hepatitis GB, Hepatitis GC, Hepatitis GD, Hepatitis GE, Hepatitis GF, Hepatitis GG, Hepatitis GH, Hepatitis GI, Hepatitis GJ, Hepatitis GK, Hepatitis GL, Hepatitis GM, Hepatitis GN, Hepatitis GO, Hepatitis GP, Hepatitis GQ, Hepatitis GR, Hepatitis GS, Hepatitis GT, Hepatitis GU, Hepatitis GV, Hepatitis GW, Hepatitis GX, Hepatitis GY, Hepatitis GZ, Hepatitis HA, Hepatitis HB, 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Hepatitis JV, Hepatitis JW, Hepatitis JX, Hepatitis JY, Hepatitis JZ, Hepatitis KA, Hepatitis KB, Hepatitis KC, Hepatitis KD, Hepatitis KE, Hepatitis KF, Hepatitis KG, Hepatitis KH, Hepatitis KI, Hepatitis KJ, Hepatitis KK, Hepatitis KL, Hepatitis KM, Hepatitis KN, Hepatitis KO, Hepatitis KP, Hepatitis KQ, Hepatitis KR, Hepatitis KS, Hepatitis KT, Hepatitis KU, Hepatitis KV, Hepatitis KW, Hepatitis KX, Hepatitis KY, Hepatitis KZ, Hepatitis LA, Hepatitis LB, Hepatitis LC, Hepatitis LD, Hepatitis LE, Hepatitis LF, Hepatitis LG, Hepatitis LH, Hepatitis LI, Hepatitis LJ, Hepatitis LK, Hepatitis LL, Hepatitis LM, Hepatitis LN, Hepatitis LO, Hepatitis LP, Hepatitis LQ, Hepatitis LR, Hepatitis LS, Hepatitis LT, Hepatitis LU, Hepatitis LV, Hepatitis LW, Hepatitis LX, Hepatitis LY, Hepatitis LZ, Hepatitis MA, Hepatitis MB, Hepatitis MC, Hepatitis MD, Hepatitis ME, Hepatitis MF, Hepatitis MG, Hepatitis MH, Hepatitis MI, Hepatitis MJ, Hepatitis MK, Hepatitis ML, Hepatitis MM, Hepatitis MN, Hepatitis MO, Hepatitis MP, Hepatitis MQ, Hepatitis MR, Hepatitis MS, Hepatitis MT, Hepatitis MU, Hepatitis MV, Hepatitis MW, Hepatitis MX, Hepatitis MY, Hepatitis MZ, Hepatitis NA, Hepatitis NB, Hepatitis NC, Hepatitis ND, Hepatitis NE, Hepatitis NF, Hepatitis NG, Hepatitis NH, Hepatitis NI, Hepatitis NJ, Hepatitis NK, Hepatitis NL, Hepatitis NM, Hepatitis NN, Hepatitis NO, Hepatitis NP, Hepatitis NQ, Hepatitis NR, Hepatitis NS, Hepatitis NT, Hepatitis NU, Hepatitis NV, Hepatitis NW, Hepatitis NX, Hepatitis NY, Hepatitis NZ, Hepatitis OA, Hepatitis OB, Hepatitis OC, Hepatitis OD, Hepatitis OE, Hepatitis OF, Hepatitis OG, Hepatitis OH, Hepatitis OI, Hepatitis OJ, Hepatitis OK, Hepatitis OL, Hepatitis OM, Hepatitis ON, Hepatitis OO, Hepatitis OP, Hepatitis OQ, Hepatitis OR, Hepatitis OS, Hepatitis OT, Hepatitis OU, Hepatitis OV, Hepatitis OW, Hepatitis OX, Hepatitis OY, Hepatitis OZ, Hepatitis PA, Hepatitis PB, Hepatitis PC, Hepatitis PD, Hepatitis PE, Hepatitis PF, Hepatitis PG, Hepatitis PH, Hepatitis PI, Hepatitis PJ, Hepatitis PK, Hepatitis PL, Hepatitis PM, Hepatitis PN, Hepatitis PO, Hepatitis PP, Hepatitis PQ, Hepatitis PR, Hepatitis PS, Hepatitis PT, Hepatitis PU, Hepatitis PV, Hepatitis PW, Hepatitis PX, Hepatitis PY, Hepatitis PZ, Hepatitis QA, Hepatitis QB, Hepatitis QC, Hepatitis QD, Hepatitis QE, Hepatitis QF, Hepatitis QG, Hepatitis QH, Hepatitis QI, Hepatitis QJ, Hepatitis QK, Hepatitis QL, Hepatitis QM, Hepatitis QN, Hepatitis QO, Hepatitis QP, Hepatitis QQ, Hepatitis QR, Hepatitis QS, Hepatitis QT, Hepatitis QU, Hepatitis QV, Hepatitis QW, Hepatitis QX, Hepatitis QY, Hepatitis QZ, Hepatitis RA, Hepatitis RB, Hepatitis RC, Hepatitis RD, Hepatitis RE, Hepatitis RF, Hepatitis RG, Hepatitis RH, Hepatitis RI, Hepatitis RJ, Hepatitis RK, Hepatitis RL, Hepatitis RM, Hepatitis RN, Hepatitis RO, Hepatitis RP, Hepatitis RQ, Hepatitis RR, Hepatitis RS, Hepatitis RT, Hepatitis RU, Hepatitis RV, Hepatitis RW, Hepatitis RX, Hepatitis RY, Hepatitis RZ, Hepatitis SA, Hepatitis SB, Hepatitis SC, Hepatitis SD, Hepatitis SE, Hepatitis SF, Hepatitis SG, Hepatitis SH, Hepatitis SI, Hepatitis SJ, Hepatitis SK, Hepatitis SL, Hepatitis SM, Hepatitis SN, Hepatitis SO, Hepatitis SP, Hepatitis SQ, Hepatitis SR, Hepatitis SS, Hepatitis ST, Hepatitis SU, Hepatitis SV, Hepatitis SW, Hepatitis SX, Hepatitis SY, Hepatitis SZ, Hepatitis TA, Hepatitis TB, Hepatitis TC, Hepatitis TD, Hepatitis TE, Hepatitis TF, Hepatitis TG, Hepatitis TH, Hepatitis TI, Hepatitis TJ, Hepatitis TK, Hepatitis TL, Hepatitis TM, Hepatitis TN, Hepatitis TO, Hepatitis TP, Hepatitis TQ, Hepatitis TR, Hepatitis TS, Hepatitis TT, Hepatitis TU, Hepatitis TV, Hepatitis TW, Hepatitis TX, Hepatitis TY, Hepatitis TZ, Hepatitis UA, Hepatitis UB, Hepatitis UC, Hepatitis UD, Hepatitis UE, Hepatitis UF, Hepatitis UG, Hepatitis UH, Hepatitis UI, Hepatitis UJ, Hepatitis UK, Hepatitis UL, Hepatitis UM, Hepatitis UN, Hepatitis UO, Hepatitis UP, Hepatitis UQ, Hepatitis UR, Hepatitis US, Hepatitis UT, Hepatitis UU, Hepatitis UV, Hepatitis UW, Hepatitis UX, Hepatitis UY, Hepatitis UZ, Hepatitis VA, Hepatitis VB, Hepatitis VC, Hepatitis VD, Hepatitis VE, Hepatitis VF, Hepatitis VG, Hepatitis VH, Hepatitis VI, Hepatitis VJ, Hepatitis VK, Hepatitis VL, Hepatitis VM, Hepatitis VN, Hepatitis VO, Hepatitis VP, Hepatitis VQ, Hepatitis VR, Hepatitis VS, Hepatitis VT, Hepatitis VU, Hepatitis VV, Hepatitis VW, Hepatitis VX, Hepatitis VY, Hepatitis VZ, Hepatitis WA, Hepatitis WB, Hepatitis WC, Hepatitis WD, Hepatitis WE, Hepatitis WF, Hepatitis WG, Hepatitis WH, Hepatitis WI, Hepatitis WJ, Hepatitis WK, Hepatitis WL, Hepatitis WM, Hepatitis WN, Hepatitis WO, Hepatitis WP, Hepatitis WQ, Hepatitis WR, Hepatitis WS, Hepatitis WT, Hepatitis WU, Hepatitis WV, Hepatitis WW, Hepatitis WX, Hepatitis WY, Hepatitis WZ, Hepatitis XA, Hepatitis XB, Hepatitis XC, Hepatitis XD, Hepatitis XE, Hepatitis XF, Hepatitis XG, Hepatitis XH, Hepatitis XI, Hepatitis XJ, Hepatitis XK, Hepatitis XL, Hepatitis XM, Hepatitis XN, Hepatitis XO, Hepatitis XP, Hepatitis XQ, Hepatitis XR, Hepatitis XS, Hepatitis XT, Hepatitis XU, Hepatitis XV, Hepatitis XW, Hepatitis XX, Hepatitis XY, Hepatitis XZ, Hepatitis YA, Hepatitis YB, Hepatitis YC, Hepatitis YD, Hepatitis YE, Hepatitis YF, Hepatitis YG, Hepatitis YH, Hepatitis YI, Hepatitis YJ, Hepatitis YK, Hepatitis YL, Hepatitis YM, Hepatitis YN, Hepatitis YO, Hepatitis YP, Hepatitis YQ, Hepatitis YR, Hepatitis YS, Hepatitis YT, Hepatitis YU, Hepatitis YV, Hepatitis YW, Hepatitis YX, Hepatitis YY, Hepatitis YZ, Hepatitis ZA, Hepatitis ZB, Hepatitis ZC, Hepatitis ZD, Hepatitis ZE, Hepatitis ZF, Hepatitis ZG, Hepatitis ZH, Hepatitis ZI, Hepatitis ZJ, Hepatitis ZK, Hepatitis ZL, Hepatitis ZM, Hepatitis ZN, Hepatitis ZO, Hepatitis ZP, Hepatitis ZQ, Hepatitis ZR, Hepatitis ZS, Hepatitis ZT, Hepatitis ZU, Hepatitis ZV, Hepatitis ZW, Hepatitis ZX, Hepatitis ZY, Hepatitis ZZ.

Inter-Assay Precision

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