Passcheck -Universal Assayed Serum Chemistry Control I & II Ref GQ-PC1-1, GQ-PC2-1

Use: IVD

Intended of Use

PassCheck control was designed for use with different brands, since Bialex Lab uses other brands for QC, and compares the results with similar methods, however, it is highly recommended to use the same reagent – Bialex.

Preparation

Add 5mL of DI Water with follow parameters: pH 7.0 +/-0.2 to each vial using a precision volumetric pipette.

Let for 30 minutes or more, and from time to time stir gently.

After opened it is stable for 7 days, except for Glucose, Bilirrubin, and Alkaline Phosphatase.

Values:

Updates will be available at www.platinium.bialexlab.com/files

Precaution

All specimens using in the PassCheck Control should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories 2nd edition, 1988 HHS Publication No (CDC)88-8395.

DBA Bialex and/or third party, certifies all individual human plasma donor units used to manufacture this lot were tested by FDA approved methods and found to non-reactive for HBsAg, HIV-1, HIV -2 and HCV.

Please see the chart in the following page,

PassCheck Multicontrol (Universal Assayed Serum Chemistry) Lot: 25PCK0161, Exp. Date: 2027.07.15, Lot: 25PCK0162, Exp.Date: 2027.05.15

Serum Analytical	Average	Level I	Units	Average	Level II
Total Bilirubin	1.00	0.30– 1.70	mg/dL	6.20	5.00-7.40
Direct Bilirubin	0.50	0.20 -0.80	mg/dL	4.70	3.60-5.80
Calcium	9.60	7.68-11.52	mg/dL	13.20	10.56-15.84
Chloride	95.00	70.00-120.00	mEq/L (mmol/L)	108.00	90.00-126.00
Cholesterol	118.00	94.40-141.60	mg/dL	257.00	212.00-302.00
Creatinine	0.99	0.79-1.18	mg/dL	4.70	3.76-5.64
Glucose	90.00	70.00-110.00	mg/dL	270.00	230-310.00
Iron	15.00	12.00-18.00	µmol/L	37.00	29.60-44.40
Magnesium	1.45	1.16-1.74	mg/dL	3.12	2.50-3.74
Phosphorus	3.60	2.88-4.32	mg/dL	7.20	5.76-8.64
Potassium	2.80	2.00 – 3.60	mEq/L (mmol/L)	4.20	3.36-5.04
Protein Total	4.00	3.00-5.00	mg/dL	7.00	5.60-8.40
Sodium	128.50	102.80-154.20	mEqL (mmol/L)	150.00	120.00-180.00
Triglycerides	110	85.00-135.00	mg/dL	220	180.00-260.00
Uric Acid	4.50	3.60-5.40	mg/dL	8.70	6.96 -10.44
Urea BUN	12.00	9.60-14.40	mg/dL	41.00	32.80-49.20
Urea UV	20.00	10.00-30.00	mg/dL	95.00	70.00-120.00
ALT/GPT (Monoreagent Mediterranean/Asian)	45	36-54	IU/L	139.00	102.00-176.00
Alkaline Phosphatase	76.00	60.00-92.00	IU/L	210.00	168.00-252.00
Amylase	210	170.00-250.00	IU/L	420.00	290-550
AST/GOT (Monoreagent Mediterranean/Asian)	80.00	60.00-100.00	IU/L	248.00	198.40-297.60

Serum Analytical	Average	Level I	Units	Average	Level II
CK	146.00	116.80-175.20	IU/L	294.00	235.20-352.80
GGT	40.00	20.00-60.00	IU/L	138.00	110.40-165.60
Albumin (Bromcresol method)	3.30	2.74 - 3.86	g/dL	4.60	3.88- 5.32
CO2	7.00	5.60-8.40	mEq/L	27.00	21.60-32.40
HDL Direct	56	40.00-72.00	mg/dL	110.00	88.00-132.00
LDL Direct	58.00	49.00-67.00	mg/dL	127.00	110.00-144.00
Lactate Dehydrogenase (*)(LDH)	220	176 - 264	U/L	600	500.00-700.00
Lipase Kinetic (Monoreagent) (America)	45.50	30-61	U/L	276	200-352
Lipase Kinetic (Monoreagent) (Mediterranean)	Pending	-----	U/L	Pending	-----

(*) Initially, the LDH analyte amendment showed a value of 550 in control 2, whereas it should be 600.