



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, Bilirubin, and Alkaline Phosphatase.

Values:

Updates will be available at www.platinum.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: 25PCK0121, 24PCK0121

Exp. Date 2027.01.01

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	0.60	0.10 -1.10	mg/dL	4.50	3.60-5.40
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	122.40	91.80-153.00	mg/dL	265.00	238.00-292.00
Creatinine	0.96	0.77-1.15	mg/dL	4.50	3.60-5.40
Glucose	97.00	77.60-116.40	mg/dL	265.00	212.00-318.00
Iron	-----	-----	-----	-----	----
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	3.12	2.50-3.74	mg/dL	7.25	5.45-9.05
Sodium	128.50	102.80-154.20	mEq/L (mmol/L)	150.00	120.00-180.00
Triglycerides	98.00	78.00-118.00	mg/dL	212.00	169.60-254.40
Uric Acid	4.30	3.40-5.20	mg/dL	7.30	5.60-9.00
Urea BUN	13.20	10.56-15.84	mg/dL	43.10	34.00-52.20
Urea UV	20.00	10.00-30.00	mg/dL	95.00	70.00-120.00
ALT/GPT (Monoreagent Mediterranean/Asian)	48.00	40.00-56.00	IU/L	145.00	115.00-175.00
Alkaline Phosphatase	70.00	40.00-100.00	IU/L	195.00	150.00-237.00
Amylase	238.00	190.00-286.00	IU/L	446.00	350.00-542.00
AST/GOT (Monoreagent Mediterranean/Asian)	62.00	49.00-75.00	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	50.00	30.00-70.00	IU/L	147.00	117.00-177.00
Albumin (Bromcresol method)	2.58	2.06-3.10	g/dL	4.55	3.64-5.46
CO2	7.00	5.60-8.40	mEq/L	27.00	21.60-32.40
HDL Direct	45.00	36.00-54.00	mg/dL	110.00	88.00-132.00
LDL Direct	55.00	43.00-67.00	mg/dL	130.00	104.00-156.00
Lactate Dehydrogenase (LDH)	220.00	160.00-300.00	U/L	430.00	320.00-540.00
Lipase Kinetic (Monoreagent)	60.00	40.00-80.00	U/L	100.00	80.00-120.00

1st Review: Jan 26th

2nd Review: Jan 30th

3rd Review: Feb 5th (Changed value in the range of Level I in the GGT)