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Data analysis for each participant generates summary and performance statistics and graphs arranged in three sections:

1. Collective summary of the current month







#### Clinical Chemistry Monthly Program

ISO/IEC 17043:2010 accredited

Sample #			Date			Lab #			Lab na	ame	
2104			Apr-21			106		XYZ Lab			
Analyte	Unit	Method	Instrument	Your Result	Mean (All)	Mean (Method)	Mean (Peer)	Compa -rator	Evaluation SDI % Dev		TEa% (Biolog. Var
Albumin g/dL		BCG	Other autoanalyzer	6	4.51	4.52	4.69	Peer	2.91	27.94%	4.07
ALP	U/L	pNPP DEA	Other autoanalyzer	177	217.37	196.23	208.45	Method	-0.86	-9.80%	12.04
ALT	U/L	ALT UV no P5P	Other autoanalyzer	119	113.05	112.55	112.99	Peer	0.42	5.32%	27.48
Amylase	U/L				249.11						14.6
AST	U/L	AST UV no P5P	Other autoanalyzer	191	185.75	186.16	187.43	Peer	0.22	1.91%	16.69
D Bilirubin	mg/dL	Dichloroaniline DCA	Other autoanalyzer	2.01	2.01	1.96	1.96	Peer	0.18	2.32%	44.55
T Bilirubin	mg/dL	Jendrassik Grof	Other autoanalyzer	5.2	4.85	4.78	4.96	All Methods	0.63	7.15%	26.94
Calcium	mg/dL	CPC	Other autoanalyzer	12.3	11.48	11.48	11.85	Method	1.23	7.11%	2.55
Chloride	mmol/L				129.53						1.5
Cholesterol	mg/dL	Cholesterol oxidase	Other autoanalyzer	206	190.12	189.94	196.29	Peer	0.53	4.95%	9.01
CK	U/L	NAC activated	Other autoanalyzer	173.8	140.40	140.40	163.97	Peer	0.41	6.00%	30.3
Creatinine	mg/dL	Jaffe kinetic	Other autoanalyzer	3.8	3.69	3.66	3.59	Peer	0.70	5.82%	8.87
GGT	U/L	G-Glutamyl-carboxy-nitroanilide	Other autoanalyzer	90	89.30	89.30	91.40	Peer	-0.19	-1.53%	22.11
Glucose	mg/dL	Glucose oxidase	Other autoanalyzer	248	258.34	254.44	259.11	Peer	-1.16	-4.29%	6.69
HDL-C	mg/dL				55.45						11.63
Iron	μg/dL				230.95						30.7
LDH	U/L	Lactate to pyruvate	Other autoanalyzer	100	370.79	267.00	286.50	Method	-12.17	-62.55%	11.4
LDL-C	mg/dL				97.69						11.9
Lipase	U/L				98.63						37.88
Magnesium	mg/dL	Colorimetric Xylidyl Blue	Other autoanalyzer	5.3	4.74	5.30	5.30	All Methods	0.98	11.86%	20.83
Phosphate	mg/dL	Phosphomolybdate UV	Other autoanalyzer	8.6	7.08	7.08	7.38	Peer	1.55	16.48%	10.11
Potassium	mmol/L	ISE K indirect	Other autoanalyzer	7.78	6.97	7.00	7.78	Method	1.92	11.12%	5.61
Proteins, T	g/dL				7.25						3.63
Sodium	mmol/L	ISE Na indirect	Other autoanalyzer	179	167.38	167.42	179.00	Method	2.50	6.92%	0.73
TIBC	μg/dL				381.51						6.83
Triglyceride	mg/dL				207.91						25.99
Urea	mg/dL	Urease UV	Other autoanalyzer	157.7	144.25	144.92	143.73	Peer	1.00	9.72%	15.55
Uric acid	mg/dL	Uricase Trinder			9.23	9.22					11.97

STATISTICAL EVALUATION:

Yellow highlight for SDI (or RMSDI): Result 2-3 SDs from comparator mean

▲ / ▼ Mark: SDI consistently >/= 2.0 ( ▲ ) or </= -2.0 ( ▼ ) for the last 3 months

The selected comparator is underlined

MEDICAL EVALUATION based on biological variation :

Optimum: %Dev < 0.5 TEa% Desirable: %Dev < TEa% Minimum: %Dev < 1.5 TEa%

Report # 106-2104/1

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U=Expanded uncertainty (in absolute units), coverage factor (K)=2

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# 2. Detailed analysis for each analyte







#### Clinical Chemistry Monthly Program

#### ISO/IEC 17043:2010 accredited

		Lab#	Sample #	<u>Date</u>	<u>Analyte</u>	Analyte Method		Instrument		
		106	2104	Apr-21	ALT	ALT UV no P5P		Other autoanalyzer		
				•		<del>_</del>		BT 4500		
Comparator Peer				Compa	<u>Y</u>	Your Deviation				
		N	<u>Mean</u>	<u>SD</u>	CV	<u>U</u>	<u>SDI</u>	<u>%Dev</u>	%Dev/TEa%	
Lab result	All Methods	41	113.05	10.04	8.89%	3.92	0.59	5.27%	0.19	
119	Method	35	112.55	10.32	9.17%	4.36	0.63	5.73%	0.21	
U/L	Peer	10	112.99	14.39	12.73%	11.37	0.42	5.32%	0.19	
			_		•	_	TEa% =	27.48		

3. Historical summary for the last 12 months







U=Expanded uncertainty (in absolute units), coverage factor (K)=2

Lab # 106									XYZ La	XYZ Lab			
Sample #	2005	2006	2007	2008	2009	2010	2011	2012	2101	2102	2103	2104	RM:
Albumin	-0.30	0.65	1.36	-0.33	-0.38	0.62	0.96	-0.14	-0.78	-0.14	-0.07	-0.59	0.0
ALP	-0.49	0.43	-0.55	-0.75	0.08	-0.40	-0.12	-0.84	0.09	0.83	1.06	-0.18	-0.
ALT	-0.74	1.08	-0.22	0.27	1.12	0.62	-0.65	-0.50	-0.11	0.47	0.51	0.07	0.:
Amylase									0.69	1.29	1.68	1.14	1.3
AST	0.33	0.58	1.00	-0.53	1.21	0.33	-1.19	-0.68	0.00	0.44	0.41	1.01	0.3
D Bilirubin		1.22	5.99	0.40	0.48	0.09	1.30	-0.10	-0.68	0.80	0.26	0.02	0.8
T Bilirubin	-0.58	1.87	1.50	0.88	0.85	0.52	0.02	0.40	0.45	0.83	0.56	0.49	0.0
Calcium	0.17	1.76	0.13	0.38	-0.25	1.25	-0.74	-0.34	-0.43	-1.30	0.31	2.12	0.3
Chloride	-0.08	0.95	-1.45	0.69	0.95	-0.68	-0.96	-0.77	0.59	0.29	0.75	1.14	0.:
Cholesterol	-1.38	-1.08	-0.40	0.34	-0.14	0.39	-0.01	-0.82	-2.85	0.27	0.06	-0.77	-0.
CK	-1.32	0.11	0.28	-0.80	-0.70	-0.24	0.19	-0.79	0.18	0.60	0.77	0.32	-0.
Creatinine	-0.49	-0.60	-0.71	0.37	0.62	0.00	0.84	0.98	-0.04	0.74	0.06	-0.03	0.
GGT	-0.27	0.91	0.69	0.95	0.40	0.69	0.15	0.19	-0.20	0.90	-0.06	-0.49	0.
Glucose	-4.70	-3.16	0.20	-0.18	-0.35	0.50	-0.10	0.87	-0.82	0.00	-0.06	-0.50	-0.
HDL-C	-0.14	-2.74	0.44	1.30	-0.63	-0.23	0.02	-1.43	-0.60	-1.39	-0.67	-1.24	-0.
Iron			-0.34	0.48	0.43	-0.17	2.02	-0.18	-0.93	-0.18	0.92	-0.12	0.:
LDH		0.52	-1.39	-0.71	0.64	-1.10	-0.12	-1.03	0.76	0.37	-0.08	-2.26	-0.
LDL-C									0.80	0.51	1.52	-0.97	0.4
Lipase													
Magnesium									-0.31	-0.24	-0.03	-1.02	-0.
Phosphate	2.75	1.62	-0.03	-0.61	-0.27	0.49	-0.11	-1.27	-1.07	-0.71	-0.40	-0.96	-0.
Potassium	0.12	0.86	1.18	0.92	1.16	0.66	0.79	0.05	0.34	-0.41	-0.26	0.09	0.4
Proteins, T	-3.26	-0.27	2.27	-0.44	0.11	-0.64	-1.27	-1.43	1.06	-0.19	-2.57	-0.30	-0.
Sodium	-0.12	2.44	0.39	0.89	1.37	0.81	0.04	0.53	0.28	-0.54	-0.34	0.56	0.
TIBC									-0.35	-0.27	1.03	0.67	0.3
Triglyceride	-0.51	0.78	0.13	-0.76	0.45	0.49	0.70	-0.62	-0.92	0.29	0.03	-1.26	-0.
Urea	-1.15	-0.10	-1.05	-0.20	0.13	0.30	-0.76	0.19	-1.06	-0.60	0.42	-2.57	-0.
Uric acid	-0.43	1.25	-0.36	1.00	0.32	-0.13	-0.13	-0.25	-0.16	-0.21	0.50	-0.27	0.0
Mean SDI	-0.63	0.41	0.39	0.15	0.33	0.18	0.04	-0.35	-0.22	0.09	0.23	-0.22	0.0

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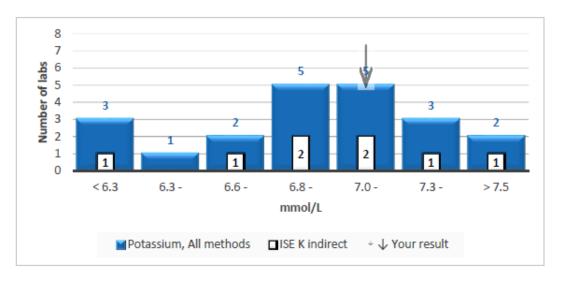
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### **Evaluation of performance**

- 1) Timely performance evaluation:
  - Criteria for performance evaluation include (Annex B.4 ISO 17043:2010):
    - Absolute value of SDI (z-score)  $\leq$  2.0 indicates "satisfactory" performance and generates no signal.
    - 2.0 < Absolute value of SDI < 3.0 indicates "questionable" performance and generates a yellow highlighted result indicating a warning signal.
    - O Absolute value of SDI  $\geq$  3.0 indicates "unsatisfactory" performance and generates a red highlighted result indicating an action signal.
  - Graphs are used to show performance:

Histograms are drawn for each analyte showing the distribution of all results submitted in this round, as well as the distribution of participants sharing the same method with the lab. The position of the lab's result in relation to the histograms is marked by an arrow.



- 2) Monitoring performance over time:
  - Criteria for performance evaluation include:
    - o Running Mean SDI (absolute value of the average SDIs over the last 12 months; RMSDI) ≤ 2.0 indicates "satisfactory" performance and generates no signal.

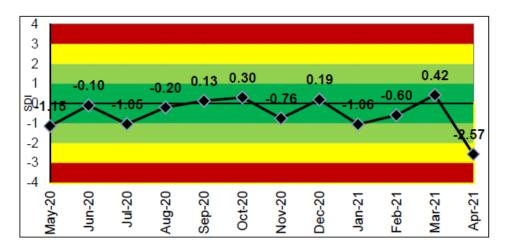


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- o 2.0 < |RMSDI| < 3.0 indicates "questionable" performance and generates a yellow highlighted result indicating a warning signal.
- $\circ$  |RMSDI|  $\geq$  3.0 indicates "unsatisfactory" performance and generates a red highlighted result indicating an action signal.
- Graphs are used to show performance over time:

Shewhart control chart for SDI shows the performance scores of each analyte over the last 12 rounds of PT scheme. To prepare this chart, the z-scores (SDI) for the laboratory are plotted as individual points, with action and warning limits set at  $\pm$  2.0 and  $\pm$  3.0.



The performance of participants is automatically commented upon using yellow or red highlights that is specefically generated for each analyte in each round for each participant. These automatic comments consider the performance of each participant compared to his peers, as well as to his previous performance. The participant is also given the chance to compare his performance against medically allowable errors. TEa% (biological variation based) and %Dev/TEa% is calculated for each measurand and values >1.0 suggests a potential for improvement:

- 1. Any analyte showing warning performane in the current cycle will be marked by yellow-highlighting its respective SDI. Red highlight prompts for an immediate corrective action by the participant.
- 2. Highlighted *mean* SDI at the end of report in each cycle means poor performance affecting the whole sample (e.g., poor storage, under/over reconstitution, delay in analysis, undue exposure to light,...).
- 3. Highlighted RMSDI for an analyte suggests a trend in its performance and prompts for an action to be taken by the participant.