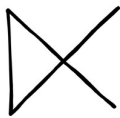


Report:	Validation Report Lateral Flow Tests for Ferritin (PremaLabs)
Report No:	36511112023
Date:	09.11.2023
Customer:	Dx365 GmbH



IFLb Laboratoriumsmedizin Berlin GmbH



Dx365 GmbH

- vertraulich / confidential -

Table of Contents

1	<i>The parties who carried out the test validation</i>	1
2	<i>Aim of the work</i>	2
3	<i>Materials and reagents</i>	2
3.1	Clinical samples	3
3.2	Performance characteristics of point-of-care Ferritin test (manufacturer data).	3
4	<i>Procedure</i>	3
4.1	Test procedure	3
5	<i>Results</i>	4
5.1	Result table	4
6	<i>Conclusion</i>	6

1 The parties who carried out the test validation

Signature	Name	Position	Company	Date
	Alexander Taran	CEO	Dx365 GmbH	29.10.2023
	Dr. Jürgen Reiner	General manager	IFLb GmbH	29.10.2023
	Dr. Oleg Tsuprykov	Research associate	IFLb GmbH	29.10.2023

Report:	Validation Report Lateral Flow Tests for Ferritin (PremaLabs)
Report No:	36511112023
Date:	09.11.2023
Customer:	Dx365 GmbH

2 Aim of the work

- Validation of one-step tests for ferritin by PrimaLabs
- Evaluation of the accuracy of point-of-care (POC) test for ferritin by PremaLabs [measured on two POC test cassette readers – Igloo™ reader by Dx365 (Berlin, Germany) and PremaLabs reader] by comparing its measurement results with the ones by a conventional clinical laboratory analyzer.

3 Materials and reagents

Table 1. Materials and reagents

	Description	Lot/SN
PremaLabs Reader	time-resolved fluorescence	SN: 94022460041 Manuf.: 2022-11
Igloo Reader	Colorimetry and time-resolved fluorescence	SN: 04251766300002
Tests	Ferritin Quantitative Test by PremaLabs	LOT: 0652208 REF: 0065-03 Exp: 2025-01
Biomaterial (clinical samples)	Clinical samples of venous serum, n = 7. Point-of-care tests were performed in not later than 24h after the measurements by a conventional clinical laboratory analyzer (in between the samples were stored at 4°C).	
Conventional clinical laboratory analyzer	The clinical samples were measured by using FERR (ferritin) OSR61203 reagent on the Beckman Coulter AU5800 clinical chemistry analyzer (Beckman Coulter, Brea, CA, USA)	FERR (ferritin) OSR61203 reagent for Beckman Coulter

Report:	Validation Report Lateral Flow Tests for Ferritin (PremaLabs)
Report No:	36511112023
Date:	09.11.2023
Customer:	Dx365 GmbH

3.1 Clinical samples

Table 2. Ferritin concentrations in clinical samples (measurements by a conventional clinical laboratory analyzer)

Patient number	Ferritin [ng/ml] ¹
1	10.7
2	20.8
3	35.6
4	77.2
5	130.3
6	165.2
7	522.5

3.2 Performance characteristics of point-of-care Ferritin test (manufacturer data)

Measuring Range:	10 – 1000 ng/ml
Lower Detection Limit:	≤ 5 ng/ml
Precision:	≤ 15 %
Specificity:	-
Sensitivity:	-
Correlation Coefficient:	99 % (r2 ≥ 0.99)

4 Procedure

4.1 Test procedure

- Transfer 5 µl of the serum to the sample buffer tube.
- Fully insert Blood Collection into buffer tube and push firmly to close tightly. Mix gently.
- Transfer 3 drops of mixing fluid to the test cassette.
- Incubate for 15 minutes and then take measurements.

¹ The Clinical samples were determined with reference method.

Report:	Validation Report Lateral Flow Tests for Ferritin (PremaLabs)
Report No:	36511112023
Date:	09.11.2023
Customer:	Dx365 GmbH

5 Results

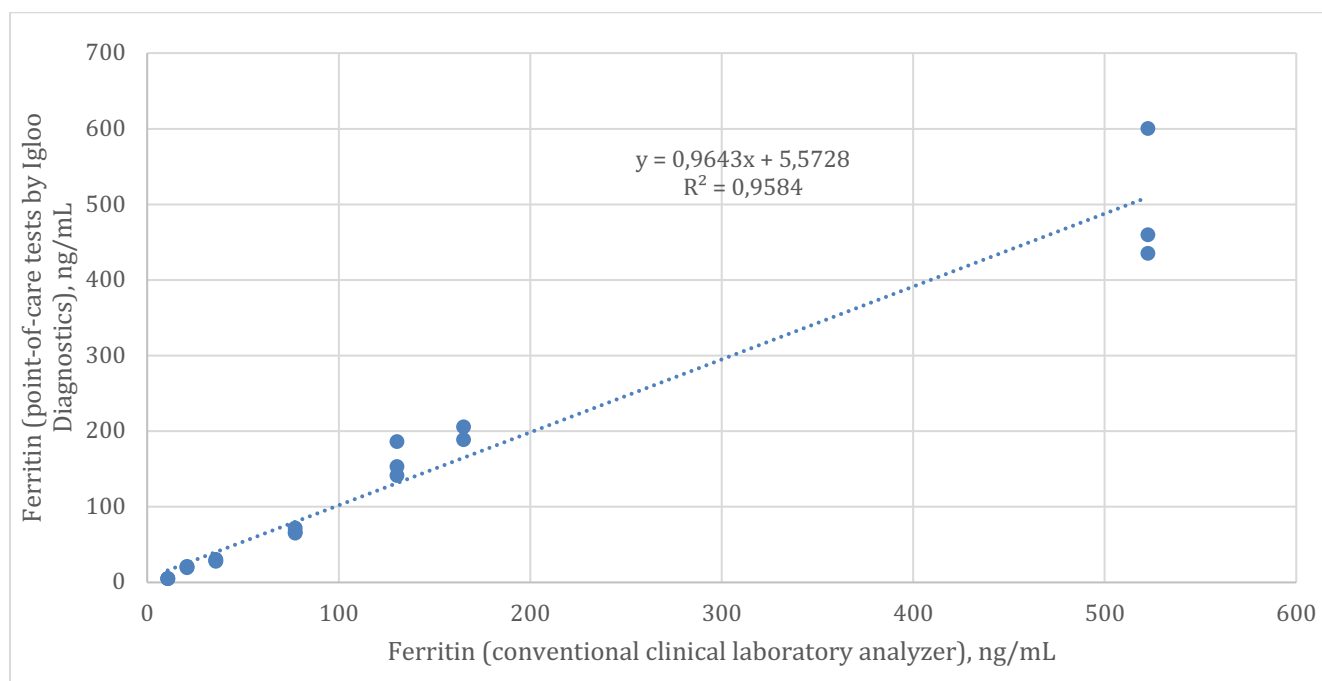
The results from device Igloo and PremaLabs reader.

5.1 Result table

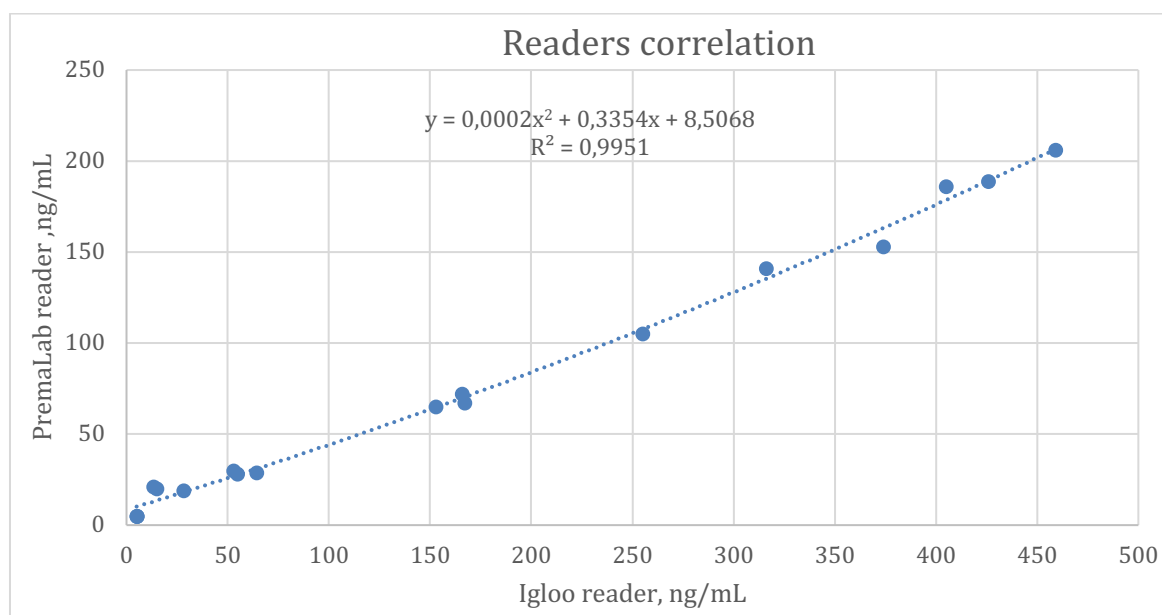
Sample ID	Repeat, №	Expected, ng/mL	PrimaLabs reader, ng/mL	Igloo reader, ng/mL
1	1	14.5	<10	24.7
	2	14.5	<10	24.5
2	1	40.5	<10	48.49
	2	40.5	14.8	45.8
3	1	72.3	13.3	71.6
	2	72.3	28.3	69.7
4	1	96	54.7	89
	2	96	64.2	105
5	1	137.4	52.9	102
	2	137.4	166	105
6	1	188.3	153	146
	2	188.3	167	232
7	1	256.2	374	299
	2	256.2	316	308
8	1	339.9	405	365
	2	339.9	459	331
9	1	407.1	255*	406
	2	407.1	426	398
10	1	557.1	>750	633
	2	557.1	>750	610
11	1	658.1	>750	633
	2	658.1		610
12	1	949.3		998
	2	949.3		950

*- An outlier measurement (we exclude it from the measurements)

Report:	Validation Report Lateral Flow Tests for Ferritin (PremaLabs)
Report No:	36511112023
Date:	09.11.2023
Customer:	Dx365 GmbH



Report:	Validation Report Lateral Flow Tests for Ferritin (PremaLabs)
Report No:	36511112023
Date:	09.11.2023
Customer:	Dx365 GmbH



6 Conclusion

We performed comparative measurements of ferritin in venous serum clinical samples (n=7, each sample was run in triplicate) using POC test PremaLabs - Ferritin Quantitative Test by PremaLabs (measured on the two readers – the PremaLabs and the Igloo™) and conventional clinical laboratory analyzer (FERR OSR61203 reagent on the Beckman Coulter AU5800).

We revealed a very strong and linear relationship between POC test-based ferritin (measured on both cassette readers – PremaLabs and Igloo™ reader) and ferritin assessed by a conventional laboratory analyzer (as evidenced by coefficients of determination R^2 of 0.98 and 0.96, respectively).

Moreover, ferritin concentrations measured by PremaLabs and Igloo™ readers also showed a very strong and linear relationship between each other (coefficient of determination R^2 of 0.995).

- End of report –