

# PRO BIO QUAL : partner of French Clinical Laboratories

**Bernard POGGI**

President of ProBioQual  
Clinical Biologist, Pharm D, EuSpLM,

**No conflict of interests**

# PRO BIO QUAL



Centre lyonnais pour la **PRO**motion de la  
**BIO**logie et du contrôle de **QUAL**ité

Non-profit non governmental association  
governed by the French law of July 1, 1901

Founded in **1972**

**By and for clinical biologists specialists in Laboratory  
medicine**

ProBioQual is a French **non-profit, non-governmental association** established in **1972** by clinical biologists to promote training and quality control for medical laboratories



**3 IQC schemes**



**53 EQA schemes**

- **> 360 Different analytes**
- **20,792 EQA programs contracted by 2023**

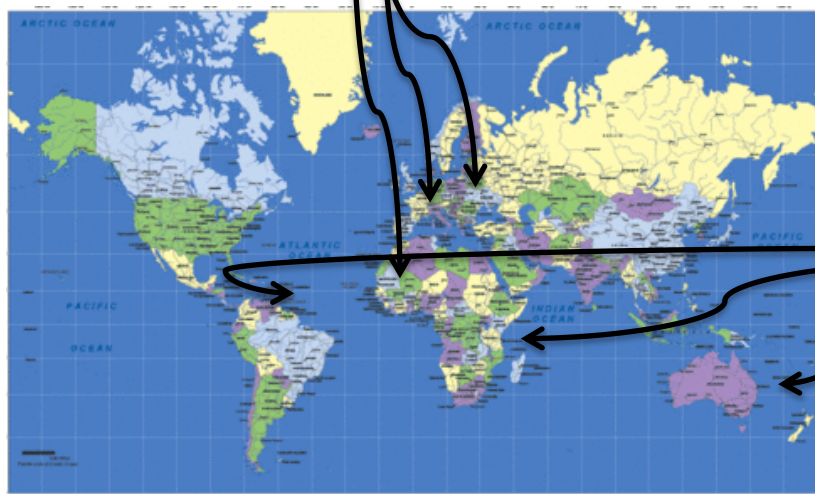


**Post Graduate Education (CPD)**

**1460 Clinical Laboratory  
Medecine sites**

**34 At the International  
In majority french speaking**

**1360 in France**



**66 DOM-CROM  
(Overseas French Departments and  
Territories)**

- **Member of the FAEEQ**



Fédération des Associations  
d'Evaluation Externe de la Qualité

**Constituted of 6 French EQAS providers :ASQUALAB, Biologie Prospective, CTCB, ABP and GBMHM and ProBioQual**

- **Member of EQALM**
- **ANSM correspondent for coding EQA results and for surveillance of laboratories par EQAS**
- **ANS correspondent (Agence National du Numérique en Santé) for the DMP (Patients' medical records)**
- **ISO 9001 certification since 2012.**
- **ISO 17043 accredited since 2014 on 31 EQAS programs in 2023:**
  - **Biochemistry**
  - **Pharmaco-toxicology**
  - **Cellular hematology**
  - **Haemostasis**
  - **Serology**

## ● **32 Volunteer expert biologists**

### – **32 clinical biologists (EuSpLM) :**

M. Beghin	C. Bon	P.J. Bondon	R. Cartier	L. Chardon
D. Cheillan	A. Citterio-Quentin	R. Cohen	S. Cohen	D. Collin-Chavagnac
C. Cuerq	C. Doche	M. Dechomet	A. Force	L. Jallades
P. Joly	L. Lacaille	M. Lety	C. Lombard	M. Lopez
R. Meley	L. Parmeland	M. Pecquet	F. Persat	M. Pettazzoni
B. Poggi	I. Quadrio	C. Roure-Sobas	F. Scherrer	B. Schubert
V. Verneau	S. Zaepfel			

### – **Statistics specialist : R. Cohen**

## ● **17 Employees**

- Computer scientist and biologist: A. Luzzati
- Clinical biologists: E. Bugni - L. Selman - B. Guillemin
- Engineer in human clinical biology: M. Presle
- Quality insurance manager: M. Presle - E. Bugni
- Administration: C. Joly
- Accounting: F. Ben Ali
- Technicians: AL. Berger - C. Blanc - O. Claudel - V. Coquet - G. Desbois - K. Martin
- Secretary: F. Callen
- Logistics officer: P. Peyre

## EQAS IN 2023 - 2024

Discipline	EQA Schemes	Year of creation
<b>CLINICAL CHEMISTRY (GENERAL AND SPECIALIZED)</b>	Clinical chemistry - Serum <b>CQH</b>	1973
	Clinical Hormonology - Serum <b>CIPO</b>	1977
	Urinary Hormonology <b>CATU, CLU</b>	1983
	Clinical chemistry - Urine <b>CMU</b>	1986
	Maternal screening Trisomy 21 <b>MSM21</b>	2002
	Cardiac markers <b>CARD</b>	2002
	Natriuretic peptides <b>CPN</b> , Creatinine clearance <b>CLAI</b>	2008
	Glycated haemoglobin <b>HBA1C</b>	2009
	Procalcitonin <b>PCT</b>	2010
	Hemoglobin electrophoresis <b>ELHB</b>	2011
	Serum protein electrophoresis <b>EPS</b>	2012
	Blood gas <b>GDS</b>	2013
	Co-oximetry <b>COOX</b>	2017
	CerebroSF biochemistry <b>LCR</b>	2017
	Catécholamines – Plasma free derivatives <b>CATE</b>	2017
	Bone markers <b>OS</b>	2021
	Fructosamin <b>FRUCTO</b>	2021
	Preeclampsia markers <b>PREE</b>	<b>2022</b>
	Bone PAL <b>PAO</b>	<b>2023</b>

## EQAS IN 2023 - 2024

Discipline	EQA Schemes	Year of creation
<b>PHARMACOLOGY TOXICOLOGY</b>	Therapeutic drugs monitoring <b>CMED</b>	1993
	Ethyl alcohol <b>CALC</b>	2000
	Urine cotinine <b>COTI</b>	2004
	Urine toxicology <b>TOXU</b>	2007
	Serum toxicology <b>TOXU</b>	2012
<b>HAEMATOLOGY HAEMOSTASIS</b>	Haemostasis <b>HEM</b>	1975
	Héparin <b>HPPO</b>	1990
	D-Dimer and Von Willebrand factor <b>HMDD</b>	2000
	Complete blood count on stabilized blood <b>NUM</b>	2009
	Complete blood count on fresh blood <b>NFR</b>	2011
	Sedimentation rate <b>VS</b>	2012
	Circulating anticoagulants <b>ACC</b>	2013
	Digitized leukocyte count <b>CYTO</b>	2015
	Réticulocytes count <b>RETI</b>	2015
	Apixaban <b>APIX</b> , Dabigatran <b>DABI</b> , Rivaroxaban <b>RIVA</b>	2017
	CSF Cytology <b>CLCR</b>	2018
	Fibrin Monomers <b>MONO</b>	2019
	Danaparoïde <b>DANA</b> , Fondaparinux <b>FONDA</b>	2020
	Anti-PF4 antibodies <b>TIH</b>	<b>2022</b>
	Fibrin and fibrinogen degradation products <b>PDF</b>	<b>2023</b>



## EQAS IN 2023 - 2024

Discipline	EQA schemes	Year of creation
<b>SEROLOGY</b>	<i>Aspergillus</i> serology and antigen detection <b>FONG</b>	2012
	<i>Cryptococcus</i> Antigen <b>CRYPTO</b>	2014
	Syphilis serology <b>SYPHI</b>	2015
	Lyme serology <b>LYME</b>	2017
	<i>Aspergillus</i> antigen detection in BAL <b>FONG-LBA</b>	2021
<b>BACTERIOLOGY</b>	Bacteriology <b>BAC</b>	2015
<b>SPERMIOLOGY</b>	Spermiology <b>SPE</b>	2018
<b>MULTI-DISCIPLINARY</b>	POCT <b>BD</b>	2018
	Serum indices <b>HIL</b>	2018

## IQC IN 2023 - 2024

Discipline	IQC	Year of creation
<b>CLINICAL CHEMISTRY</b>	Seric biochemistry (specific proteins) <b>CQPS</b>	1973
	Maternal screening of fetal Trisomy 21 <b>MSMPE</b>	2010
<b>HAEMOSTASIS</b>	Haemostasis <b>HMPE</b>	1975

## Clinical laboratories accreditation support

### Since 2011

- ✓ Annual summary of their ProBioQual EQA schemes participation
- ✓ Excel format extraction of their EQA data
- ✓ IQC data external exploitation (accuracy, precision)

### Since 2015



- ✓ Long Term uncertainty in measurement (UMLT) estimation from EQA results of medical laboratories (Matar G, *et al.* 2015. Uncertainty in measurement for 43 biochemistry, immunoassay, and hemostasis routine analytes evaluated by a method using only external quality assessment data. *Clin Chem Lab Med* 53: 1725–1736)
- ✓ Direct internet transmission of results for qualitative control
- ✓ Direct transfer of all EQA data from clinical laboratories by Hprim® protocol

### Since 2018

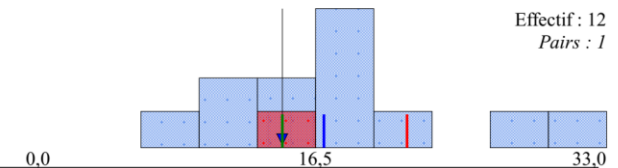
- ✓ Assistance program for staff qualification in cytology of different biological liquids






# Report for labs for LTUM

## Biochimie : Biochimie générale et spécialisée

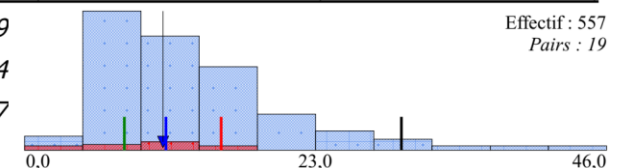
5' Nucléotidase  108 11 **14,6 %** 1er quartile  **14,6 %**  
Médiane  **17,0 %**  
3e quartile  **21,7 %**

5'NU Rf Diazyme (DIAZYME LABORATORIES) sur  
Dimension Vista [JC/DFJ]



ACE  108 22 **10,9 %** 1er quartile  **7,8 %** 6,9  
Médiane  **11,1 %** 9,4  
3e quartile  **15,6 %** 10,7  
U<sub>souh</sub>  **29,7 %**

Vista - CEA (SIEMENS Healthcare Diagnostics) sur  
Dimension Vista [SQ/DFJ]



- All 3 2024 IQC products are **CE marked** (Regulation (EU) 2017/746 / Directive 98/79/CE)
- **ISO 9001** certification since 2012
- **ISO 17043** accreditation since 2014. **31** accredited EQA schemes:
  - Clinical chemistry (CARD, CLAI, CLU, CMU, CPN, CQH, CIPO, ELHB, EPS, FRUCTO, GDS, HBA1C, LCR, PCT),
  - Pharmacology - Toxicology (CMED, CALC and TOXS),
  - Coagulation (ACC, APIX, DABI, DANA, FONDA, HMPO, HPPO, HMDD et RIVA),
  - Haematology (NUM, RETI, VS et NFR).
  - Serology : LYME
  - Different biological fluids : total blood, plasma, serum, CSF, urine

PBQ is one of 4 French EQAS organisers accredited to ISO 17043

French law on clinical biology is different of others countries : All clinical Laboratories have to be accredited ISO 15189 :

- Accuracy of all lab analysers have to be verified by an EQAS
- POCT (in french biologie délocalisée) is clearly reserved to emergency
- and all POCT analysers have to be under control of the laboratory.

Since 2018 : the only French EQAS organiser to propose a POCT EQAS program using total fresh blood for hematology, biochemistry (spiked total blood on 7 analytes) and hemostasis (INR) with around 500 users, with a small verified stability (48h).

## PROSPECTIVES

### New EQA Schemes under development for 2024

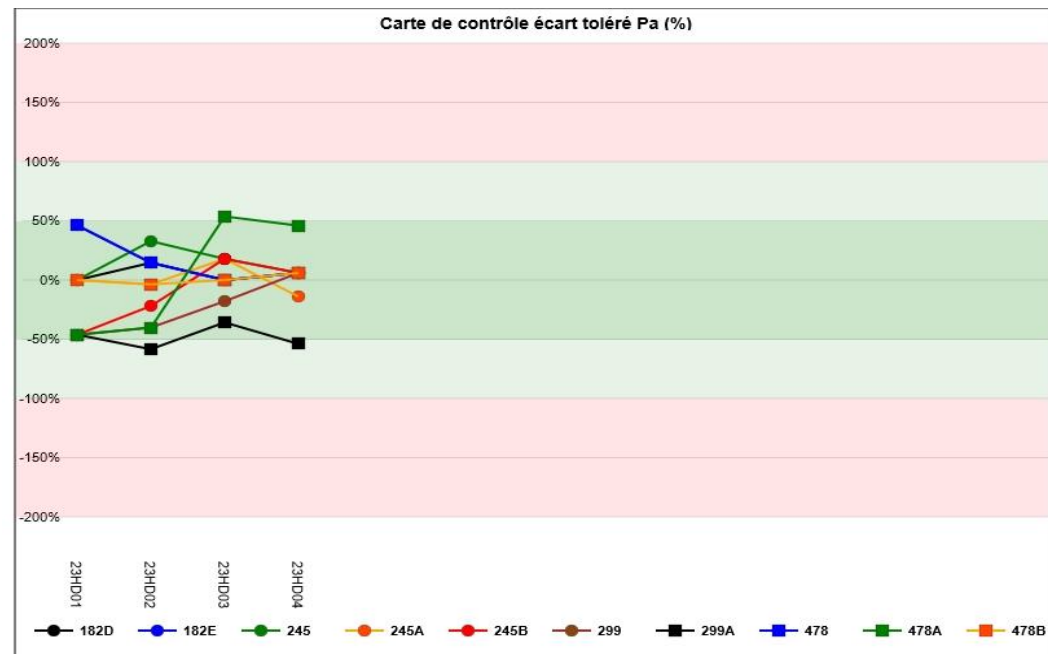
- *Helicobacter pylori* –  $^{13}\text{C}$  Urea test
- Determination of urinary ethylglucuronide in urine

### Projects :

- Virtual microscopy in the fields of cytology, bacteriology, parasitology, ...
- Other serologies other than all current pathologies developed by other French EQA organisers
- Circulating DNA
- Test METAGLUT1 (mellitus iabetis)
- NEPHROCHECK

# Under development

- Comparability of the different analysers of one clinical lab on the same analyte using on the same samples of an EQAS; the lab defined the maximum tolerable deviation of results for him; visual reporting :



Groupes techniques/pairs	Codage	Histogramme	n	Cible	CV	E/M%	Limites
ENSEMBLE DES RESULTATS	Z		1372	91,7	6,5		76,9 - 106,5
• TECHNIQUES IFCC avec PLP (inclus ou ajouté) •	N		1054	92,6	4,8	1,0	77,7 - 107,5
ABBOTT Alinity c • Activated ALAT (NQ1)	NQ1 DZK		168	94,0	2,5	2,5	78,9 - 109,1
ABBOTT Architect c • Activated ALAT (NQ2)	NQ2 DZG, DZH, DZI		118	92,0	2,8	0,3	77,2 - 106,8
BECKMAN COULTER AU system (N6)	N6 DE		117	95,3	3,5	3,9	80,0 - 110,6
RF BIOSYSTEMS (NS)	NS		2	96,5	/		
ROCHE Cobas & Integra Réactif ALTP/ALTL/ALTPM	N41, N42, N43, N44, N45		375	89,1	3,1	-2,8	74,8 - 103,4
• dont Integra (N41)	N41 DQH, DQI, DQL		9	87,2	2,7	-4,9	73,0 - 101,4
• dont Cobas c 501 • c 502 Rf ALTL (N41) / Rf ALTP (N42)	N41, N42 DQP		116	87,9	2,4	-4,1	73,7 - 102,1
• dont Cobas c 701 • c 702 Rf ALTPM (N44)	N44 DQR		90	89,1	2,8	-2,8	74,8 - 103,4
• dont Cobas c 303 • c 503 (N45)	N45 DQT, DQW		154	90,5	3,0	-1,3	75,9 - 105,1
ROCHE Cobas c Réactif ALTP2 • Cobas pro c503 (N5)	N5 DQT		35	89,7	2,5	-2,2	75,3 - 104,1
SIEMENS Advia/Atellica CH 930 (NE1, NE2, NEC)	NE1, NE2, NEC DT		152	97,0	2,9	5,8	81,4 - 112,6
• dont Advia Rf ALTP5P et ALTPLe (NE1, NEC)	NE1, NEC DT		5	97,8	/		
• dont Atellica CH Rf ALTPLe (NE2)	NE2 DTP		147	97,0	2,8	5,8	81,4 - 112,6
SIEMENS Vista Rf ALTI (NC1)	NC1 DFJ		29	97,1	2,6	5,9	81,5 - 112,7
SIEMENS Dimension RXL, EXL, XPand Rf ALTI (NC2)	NC2 DFG, DFH, DFI, DEK		58	96,1	4,0	4,8	80,6 - 111,6
• TECHNIQUES "NON-IFCC" sans PLP •	S		245	84,3	3,7	-8,1	70,7 - 97,9
ABBOTT Architect/ Alinity Rf ALT (SQ1, SQ2)	SQ2, SQ1 DZH, DZI, DZG, DZK		15	87,5	3,7	-4,6	73,3 - 101,7
ABBOTT Architect/ Alinity Rf ALT2 (SF, SG)	SF, SG DZH, DZI, DZG, DZK		6	82,7	/		
BECKMAN COULTER AU system (S6)	S6 DE		1	94,0	/		
HORIBA ABX Penra (SK)	SK DAP, DAQ		3	89,0	/		
ROCHE Cobas & Integra (S41, S43, S44, S45)	S41, S43, S44		196	83,5	2,8	-8,9	70,1 - 96,9

# Examples of statistical analysis

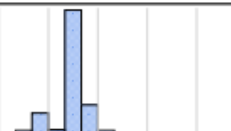
















23BA32 / ALAT (TGP) (U/L 37°C)

Limites acceptables à ± 16,1 % (EFLM souhaitable)  
Statistiques robustes (algorithme A - norme ISO 13528:2022)

Groupes techniques/pairs	Codage	Histogramme	n	Cible	CV	E/M%	Limites
• dont Integra Rf ALTL sans PLP (S41)	S41 DQH, DQI, DQL		18	81,2	2,4	-11,5	68,1 - 94,3
• dont Cobas c 501 • c502 Rf ALTL sans PLP (S41)	S41 DQP		127	83,8	2,4	-8,6	70,3 - 97,3
• dont Cobas c 701 • c 702 Rf ALT sans PLP (S44)	S44 DQR		46	83,8	3,1	-8,6	70,3 - 97,3
SIEMENS Advia Rf ALT sans PLP (SE1)	SE1 DT		10	100,6	2,8	9,7	84,3 - 116,9
SIEMENS Atellica CH Rf ALT sans PLP (SE2)	SE2 DTP		10	96,6	3,3	5,3	80,8 - 112,4
THERMO SCIENTIFIC Rf TGP monoréactif sans PLP (SJ)	SJ DB		4	93,6	/		
• REFLECTOMETRIE •	3		70	101,5	4,0	10,7	
ORTHO Vitros (ALT) (3K1 • 3K2 • 3K3)	3K1, 3K2, 3K3 FK		57	102,4	3,4	11,7	85,9 - 118,9
• dont Vitros ALT (3K1)	3K1 FK		44	102,7	3,3	12,0	86,2 - 119,2
• dont Vitros ALT V (3K2)	3K2 FK		6	101,0	/		
• dont Vitros ALT V-ASTV (3K3)	3K3 FK		7	101,3	2,1	10,5	84,9 - 117,7
FUJIFILM Fuji Dri-Chem (3S)	3S FJA		13	97,1	4,1	5,9	81,2 - 113,0
AUTRES	DSK, DSP		3	73,0	/		
LITE ON technology • Skyla HB1 (DSK)	DSK SKA		1	74,0	/		
ABAXIS • Piccolo Xpress (DSP)	DSP SAP		2	73,0	/		



Groupes techniques/pairs	Codage	Histogramme	n	Cible	CV	E/M%	Limites
ENSEMBLE DES RESULTATS	V		490	24,79	8,2		
ABBOTT Architect / Alinity	RJ1, RJ2		113	25,32	5,8	2,1	17,42 - 33,22
- dont Architect	RJ2 U4Y		36	25,41	5,3	2,5	17,48 - 33,34
- dont Alinity	RJ1 U4Z		77	25,26	6,1	1,9	17,38 - 33,14
BECKMAN Access/Dxl/DxC	QE		53	13,32	6,8	-46,3	9,16 - 17,48
- dont Access/Access2	QE ULA		2	13,95	/		
- dont Dxl 600 / 800	QE UCD		51	13,29	6,9	-46,4	9,14 - 17,44
BIOMERIEUX Vidas/MiniVidas/Vidas 3	DB UGV, UGW, UGT		8	22,55	9,4	-9,0	15,27 - 29,83
DIASORIN Liaison	S8 UKW, UKV		4	25,89	/		
ORTHO CLINICAL Vitros	P5 U4V, U4W, FK1, FKK		14	23,05	8,2	-7,0	15,75 - 30,35
ROCHE Elecsys/Modular/Cobas	RD1, RD2		207	25,83	4,2	4,2	17,77 - 33,89
- dont Cobas e 411	RD1 UWL		4	28,80	/		
- dont Cobas e 601/e 602	RD1 UWR, UWT		69	26,34	3,9	6,3	18,12 - 34,56
- dont Cobas e 402/e 801	RD2 UWS, UWW		134	25,53	3,9	3,0	17,56 - 33,50
SIEMENS Advia Centaur CP/XP/XPT	SI U4E, U4S		14	23,27	4,9	-6,1	15,97 - 30,57
SIEMENS Atellica	SW U4U		59	23,91	6,3	-3,5	16,45 - 31,37
SIEMENS Dimension Vista	SQ DFJ		6	26,48	/		
THERMO FISHER Kryptor	SN		11	24,51	3,6	-1,1	16,83 - 32,19

&lt; 0,00 15,86 31,72 47,58 63,44 &gt;

## 23HA13 / Fibrinogène (g/L)

Limites acceptables à  $\pm 12,0\%$  (ProBioQual)  
Statistiques robustes (algorithme A - norme ISO 13528:2022)

Groupes techniques/pairs	Codage	Histogramme	n	Cible	CV	E/M%	Limites
ENSEMBLE DES RESULTATS	A		898	2,419	5,5		2,129-2,709
METHODES VON CLAUSS	B3, D1, G1, H1, I1, J4, L1, R1, S2, W1,		854	2,413	5,4	-0,2	2,123-2,703
HYPHEN BIOMED Fibrinphen	W1		8	2,330	2,5	+3,7	2,046-2,614
-- HYPHEN BIOMED Fibrinphen/Sysmex CS	W1 PB5		7	2,336	3,0	+3,4	2,048-2,624
-- HYPHEN BIOMED Fibrinphen/Sysmex CN	W1 PB7		1	2,310	/		
HYPHEN BIOMED • Fibrinphen LRT	W2		14	2,558	7,2	5,7	2,227-2,889
-- HYPHEN BIOMED • Fibrinphen LRT/Sysmex CS	W2 PB5		2	2,435	/		
-- HYPHEN BIOMED • Fibrinphen LRT/Sysmex CN	W2 PB7		12	2,580	6,5	6,7	2,248-2,912
IL/WERFEN HemosIL Fibrinogen-C	G1		167	2,394	6,0	+1,0	2,107-2,681
-- IL/WERFEN HemosIL Fibrinogen-C/ACL	G1 PG2		1	2,300	/		
-- IL/WERFEN HemosIL Fibrinogen-C/ACL TOP	G1 PG4		166	2,395	6,0	+1,0	2,108-2,682
IL/WERFEN HemosIL QFA Thrombin 2 mL	H1		44	2,250	4,8	+7,0	1,980-2,520
-- IL/WERFEN HemosIL QFA Thrombin/ACL TOP	H1 PG4		44	2,250	4,8	+7,0	1,980-2,520
SIEMENS Réactif Dade Thrombine	D1		80	2,325	7,1	+3,9	2,046-2,604
-- SIEMENS Réactif Dade Thrombine/Sysmex CS	D1 PB5		45	2,281	6,9	+5,7	2,007-2,555
-- SIEMENS Réactif Dade Thrombine/Atellica COAG360	D1 PB6		7	2,263	5,9	+6,4	1,963-2,563
-- SIEMENS Réactif Dade Thrombine/ACL TOP	D1 PG4		15	2,413	4,7	-0,2	2,115-2,711
-- SIEMENS Réactif Dade Thrombine/STA	D1 PJ5, PJ7, PJ8		9	2,489	2,3	2,9	2,187-2,791
-- SIEMENS Réactif Dade Thrombine/STA-R	D1 PJ8		9	2,489	2,3	2,9	2,187-2,791
-- SIEMENS Réactif Dade Thrombine/Sysmex CA	D1 PW1		4	2,038	/		
STAGO STA Liquid Fib	J4		540	2,439	4,3	0,8	2,146-2,732
-- STAGO STA Liquid Fib/ST4, Start 4 à 8	J4 PJ1		7	2,440	8,8	0,9	2,084-2,796
-- STAGO STA Liquid Fib/STA	J4 PJ5, PJ7, PJ8		514	2,443	4,2	1,0	2,150-2,736

< 0,969 1,694 2,419 3,144 3,860 >

# Continuous Professional Development

**QUALIOPI certification for the training of laboratory technicians and clinical biologists since 2020.**

CPD processus in ProBioQual offers :

- Recurrent presential trainings such as « uncertainty in measurement of quantitative analytical procedures » or « management of quality control programmes »
- ANDPC- approved presential trainings, for periodical validation of clinical biologists and lab technicians :
  - In 2023, 2 trainings concerning the diagnostic strategy and the role of biological tests in the management and monitoring of :
    - Cardiovascular diseases and their risk factor
    - Anemias
  - In 2024, we will propose 2 supplementary trainings on cancer and antibioresistance

# Thank you for your attention

[B.poggi@probioqual.com](mailto:B.poggi@probioqual.com)