

Mpn UNILAB LTD

1998: whats this accreditation
business all about?

1999: The beggining !

ISO/IEC GUIDE25- EN 45001

1999-2005-2017: ISO/IEC 17025

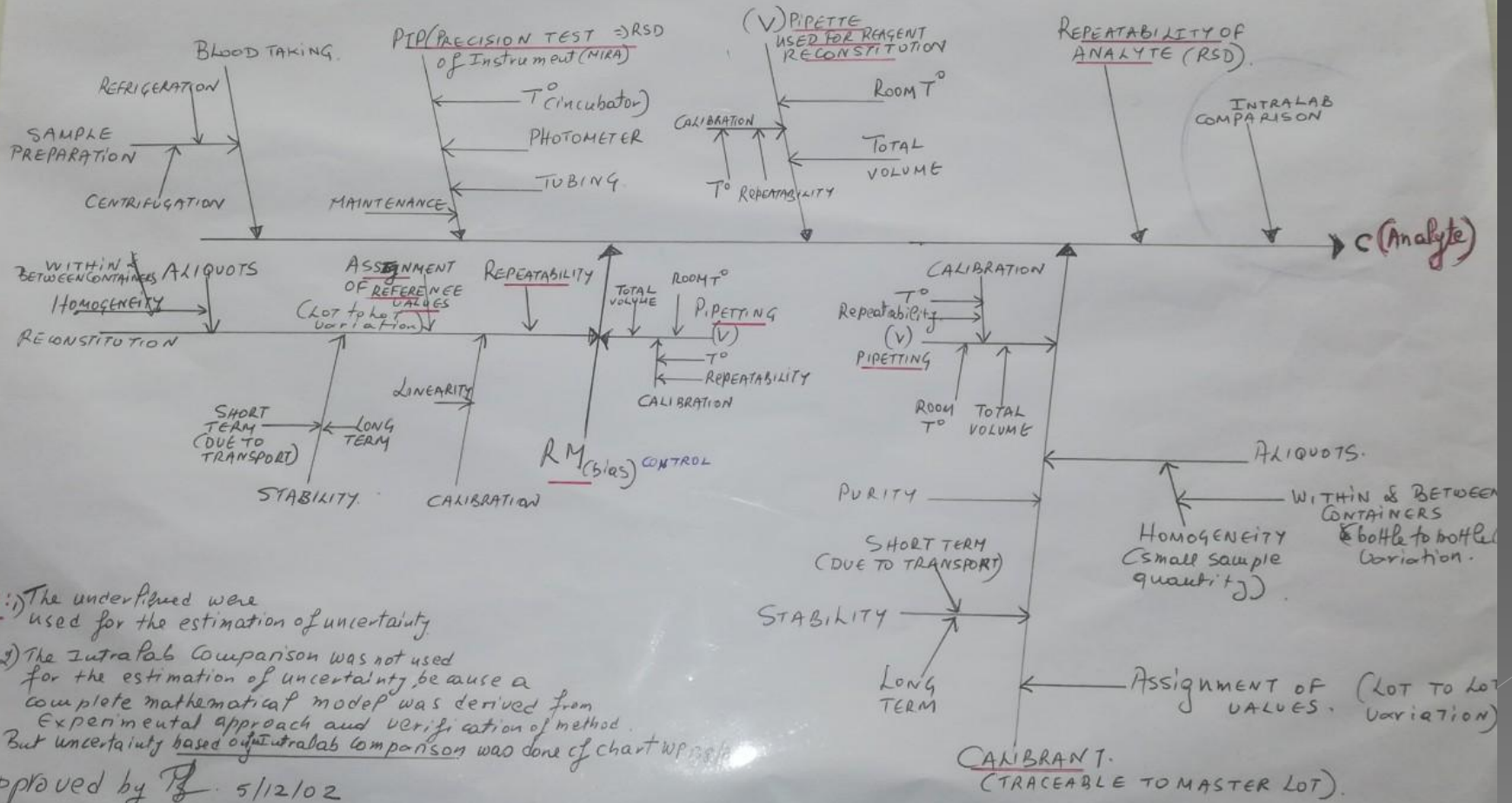
2003-2007-2012: ISO/IEC 15189

WP 141

MIRA & ISE WP 6

CAUSE AND EFFECT DIAGRAM (Fish bone presentation)

BOTTOM UP



Rq: 1) The underlined were used for the estimation of uncertainty

2) The Intralab Comparison was not used for the estimation of uncertainty because a complete mathematical model was derived from experimental approach and verification of method. But uncertainty based on intralab comparison was done of chart WP 141

Approved by P. 5/12/02

UNCERTAINTY.....

The estimation of uncertainty was based on 3
 - 10 readings (to determine standard deviation) and 100 readings (to determine standard deviation)
 - 100 readings were used to determine the standard deviation of the mean (SDM) and the standard error of the mean (SEM)

ESTIMATION OF UNCERTAINTIES

Type of scale used = 3 part differential

A small F uncertainty due to WP 101 (INSTRUMENT = HENKES 2010D)

ANALYTE	UNITS	RANGE OF TEST	MEAN VALUE	SD	SEM	RELATIVE SD (%)	RELATIVE SEM (%)	RELATIVE UNCORRECTED UNCERTAINTY (%)	RELATIVE CORRECTED UNCERTAINTY (%)	UNCERTAINTY	RELATIVE UNCORRECTED UNCERTAINTY (%)	RELATIVE CORRECTED UNCERTAINTY (%)	UNCERTAINTY	RELATIVE UNCORRECTED UNCERTAINTY (%)	RELATIVE CORRECTED UNCERTAINTY (%)
WBC	$10^9 L^{-1}$	11-10-20000 10-2500 ± 2%	16.58	0.461	0.019	2.4	0.112	3.86 × 10 ⁻³	4.489 × 10 ⁻³	0.062	0.062 × 16.6 = 0.967	1.934	15.6 ± 1.934 (13.6 - 17.536)	11.5	
RBC	$10^{12} L^{-1}$	2.5-10-20000 10-2500 ± 2%	4.63	0.1	0.01	4.63	0.215	4.66 × 10 ⁻⁴	3.168 × 10 ⁻⁴	0.0274	0.0274 × 2.16 = 0.060	0.12	2.16 ± 0.12 (2.04 - 2.28)	2.1	
Hgb	g dl ⁻¹	10-20-20000 10-2500 ± 2%	13.9	0.28	0.019	13.9	0.136	4.05 × 10 ⁻⁴	5.041 × 10 ⁻⁴	0.021	0.021 × 6.3 = 0.132	0.264	6.3 ± 0.264 (6.036 - 6.564)	6.1	
Hct	%	10-20-20000 10-2500 ± 2%	36.1	1.44	0.089	36.1	0.247	1.59 × 10 ⁻³	3.64 × 10 ⁻⁴	0.044	0.044 × 15.3 = 0.673	1.346	15.3 ± 1.346 (13.954 - 16.646)	15.1	
MCV	fL	100-120-20000 10-2500 ± 2%	78	2.30	0.112	78	0.144	8.71 × 10 ⁻⁴	1.14 × 10 ⁻⁴	0.031	0.031 × 71 = 2.201	4.402	71 ± 4.402 (66.598 - 75.402)	70.8	
MCH	pg	100-120-20000 10-2500 ± 2%	30.0	1.15	0.078	30.0	0.260	1.97 × 10 ⁻³	3.345 × 10 ⁻⁴	0.042	0.042 × 29.3 = 1.230	2.46	29.3 ± 2.46 (26.84 - 31.76)	29.1	
MCHC	g dl ⁻¹	100-120-20000 10-2500 ± 2%	38.5	1.732	0.097	38.5	0.252	2.02 × 10 ⁻³	3.45 × 10 ⁻⁴	0.048	0.048 × 41.4 = 1.987	3.974	41.4 ± 3.974 (37.426 - 45.374)	41.2	

USE OF CONTROLS

- ◉ INTERNAL-POOLS
- ◉ EXTERNAL- INSTRUMENT SPECIFIC, OTHER SCHEMES
- ◉ TESTED EXTERNAL QC's
- ◉ PARALLEL SAMPLES TESTING WITHIN LABS

«POOLS»

- ◉ TESTED SERA POOLED TOGETHER
- ◉ CENTRIFUGED TWICE
- ◉ TESTED FOR HIV, HEPB, HEPC, VDRL.
- ◉ ALIQUOTS KEPT IN THE FREEZER
- ◉ INITIAL USE IN PARALLEL WITH CONTROLS OF KNOWN VALUES
- ◉ INCLUSION CRITERIA (Non hemolysed, non icteric, no plasma, positive consent)

ADVANTAGES OF POOLS

- THEY BEHAVE LIKE BIOLOGICAL SAMPLES WITHOUT THE MATRIX EFFECTS OF EQC's BECAUSE OF THE PRESENCE OF ALBUMIN
- THEY REPRESENT THE TRUE POPULATION OF EACH LABORATORY'S PATIENTS
- THEY ARE THE MEAN VALUE OF THE TOTAL
- CAN BE SEPARATED INTO LEVELS
- THEY ARE A VERY GOOD INDICATORS OF STABILITY, REPEATABILITY
- THEY ARE VERY STABLE AT -20°C
- NO COST
- THEY HAVE PROVED TO BE VERY RELIABLE TOOLS

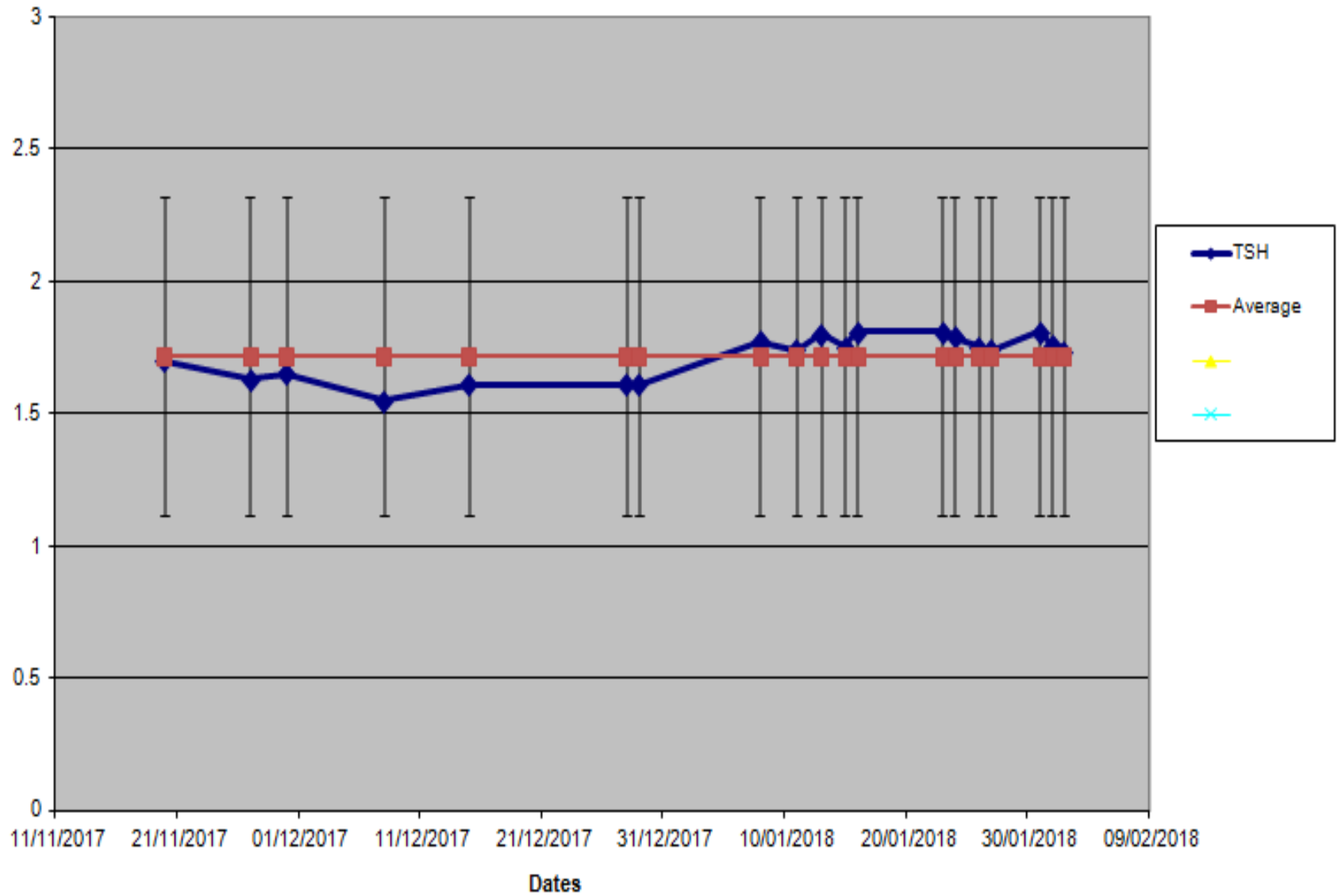
DISADVANTAGES OF POOLS

- BY THEIR OWN THEY DONOT HAVE REFERENCE INTERVALS
- THEY NEED TO BE RUN INITIALLY WITH KNOWN REFERENCE MATERIALS

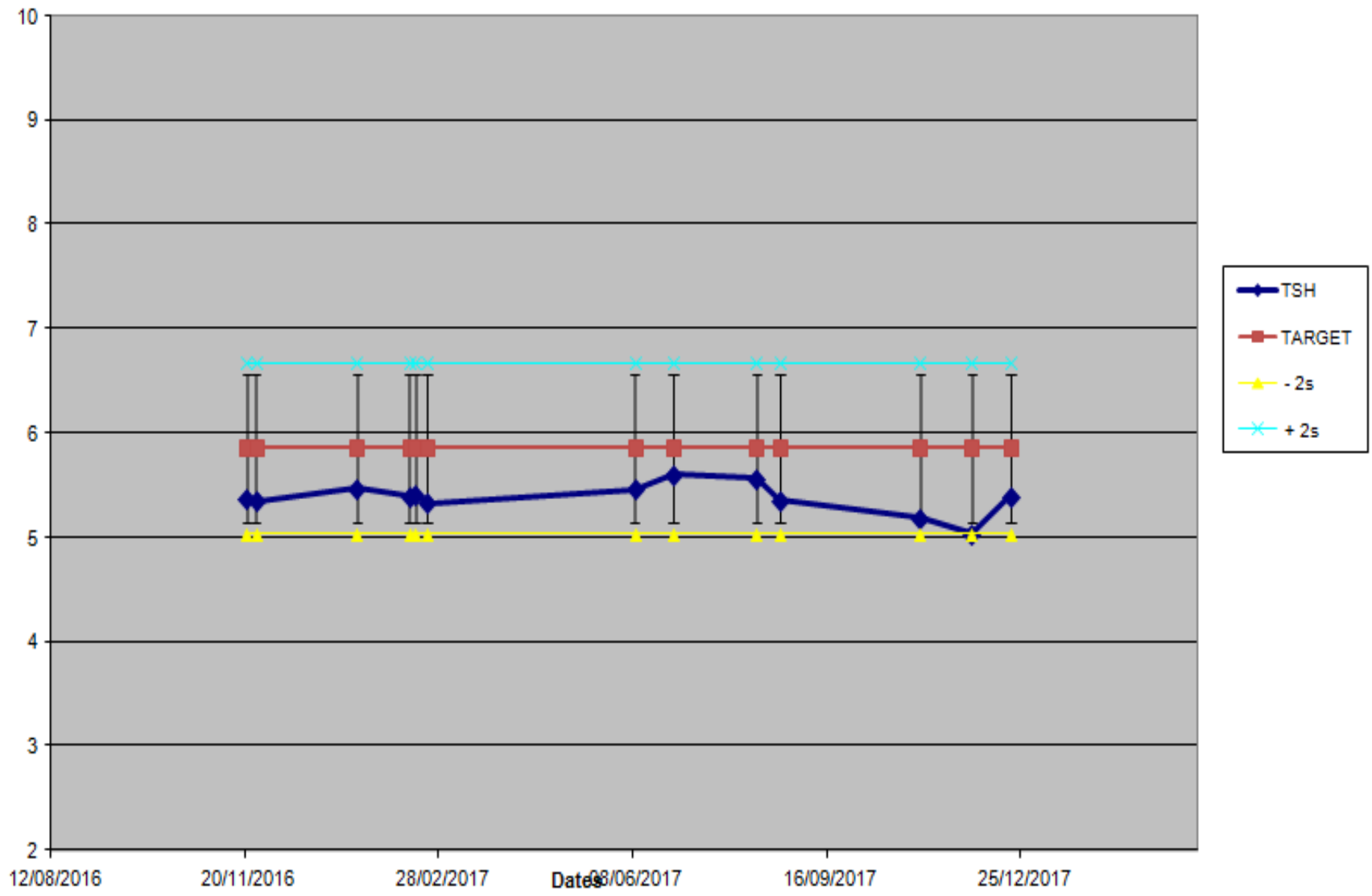
Microiological isolates used as control material

- Isolates from the clinical section which have been identified and confirmed by the Vitek2 system are stored aliquoted in nutrient broth & 10% glycerol at -20°C
- Used as positive controls
- Used to verify complience of culture media
- Used in studies for the estimation of uncertainty (food/water)

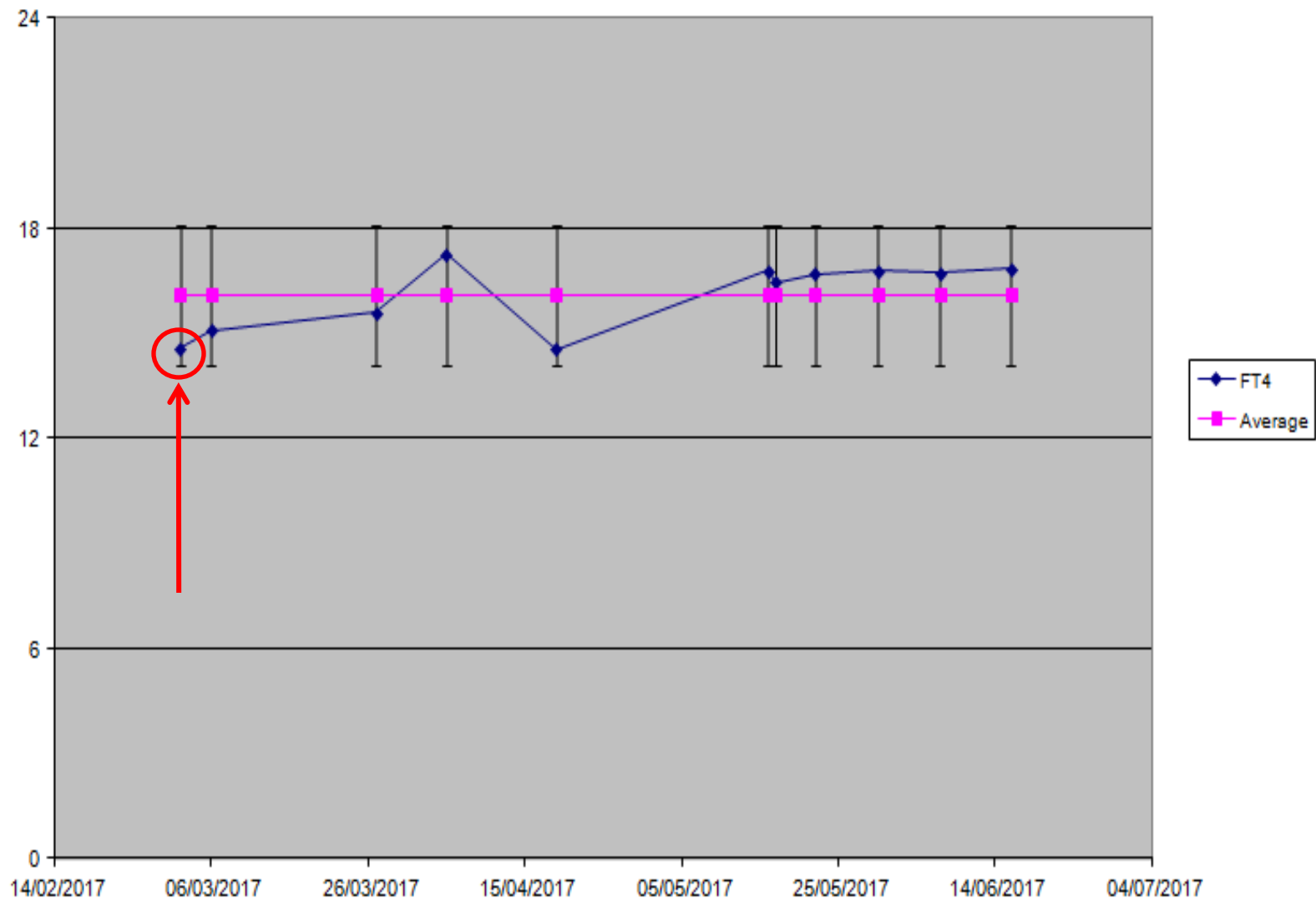
TSH-POOL69



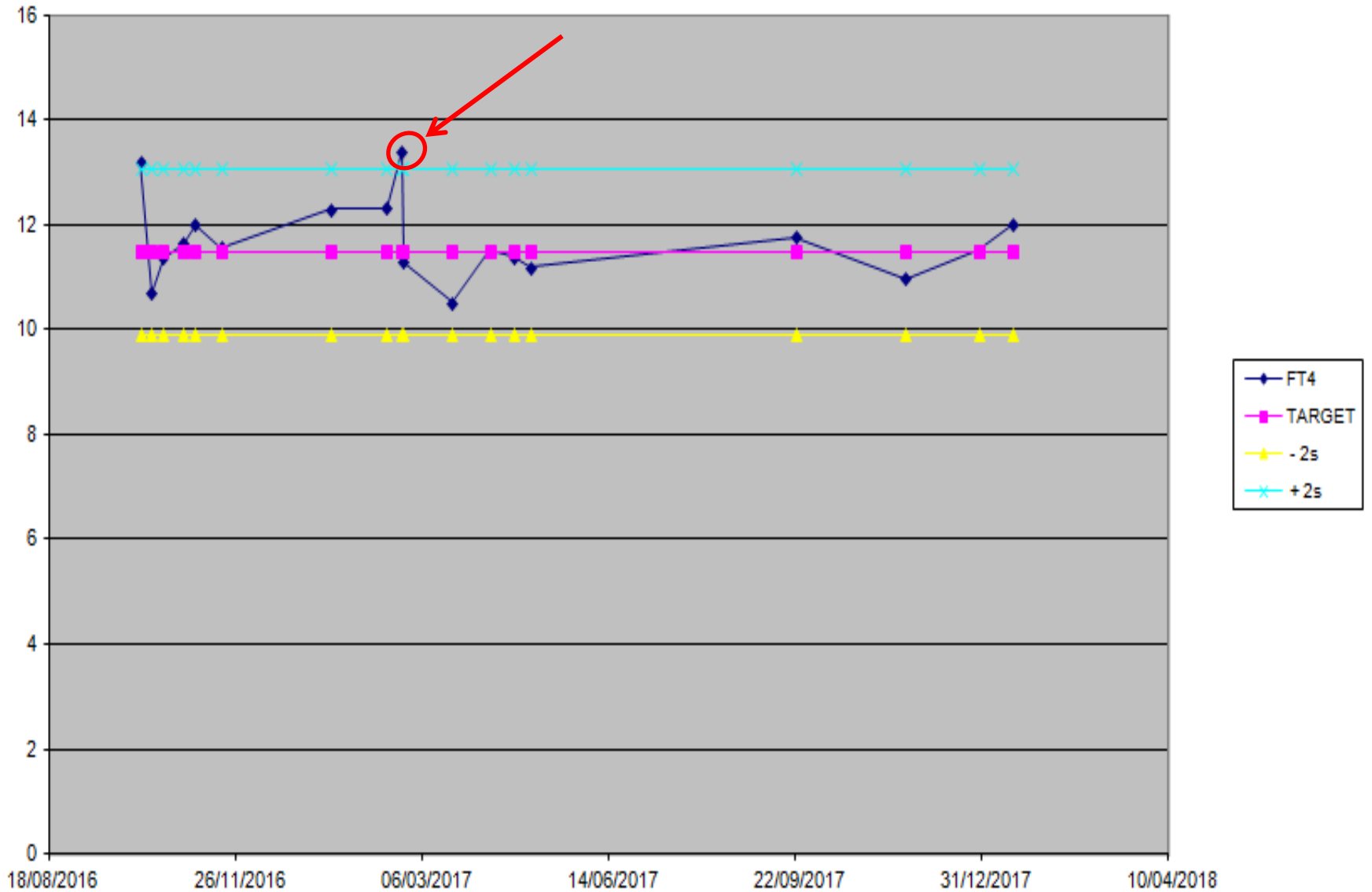
TSH-40312



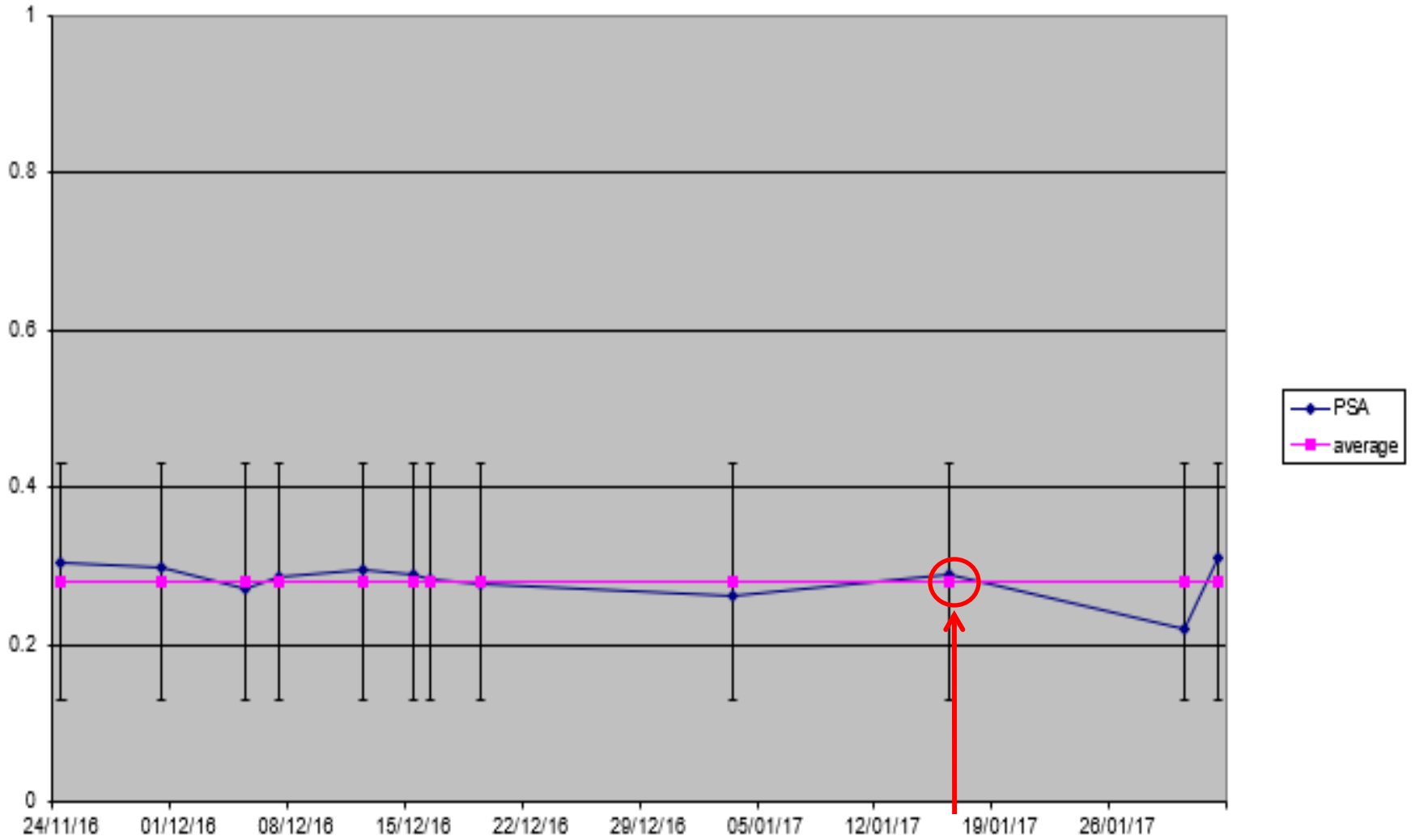
FT4- POOL 67



FT4 40311



PSA-POOL66



PSA 40311

