



LIVE SMARTER

Monthly Technical Review (Oct 2020 Data)

Flex CFT
25 Nov 2020

Agenda

1. Review of last MTR minutes & action items
2. First Pass Yield
 - Overall Results & individual instrument results
 - Instrument > targets (does not meet Waters targets or having downtrend)
 - Improvement actions & effectiveness (if any)
3. Manufacturing readiness
 - Training review and competencies updates (na for this session)
 - Manufacturing Engineering Issues / Updates
 - Test Engineering Issues / Updates
 - TMD Updates
4. Quality (trending, analysis of issues (repeated case), updates / actions taken)
 - Suppliers
 - LAR
 - SCAR
 - Audit (schedules, audit results, findings and closure etc)
 - In Process
 - NCR
 - CAPA
 - Quality alerts
 - Customers & field complaints
 - QMS updates (na for this session)
5. Others
 - AOB

Review of last MTR minutes & action items

#	Date	Item	Responsible	Status
1	15Jul20	<u>PDA - Loss comm</u> - As part of Data analysis, only testers 8, 11 and 13 are being used. From the current evaluation data result, these 3 testers showing low yield which impacted the Jun'20 yield. The collection of 600 data points to be completed by end of this month (Jul) and it is expected to have a low yield result for PDA in month of Jul.	For info	For info
	25Aug20	Data collection activity completed. Summary: - TE82882-9, 10, 14 showing better yield (9% to 20% of units failed Loss Comm) - TE82882-8, 11, 13 showing lower yield (43% to 45% of units failed Loss Comm)	For Info	For Info
	26Aug20	- Hua Zhen to share the email from Eric Turner (Waters Milford) to update on this issue.	Hua Zhen	Closed
	15Sep20	- Eric Turner made change / adjustment to below and continual feedback is still on-going.: > TE82882-8 Eric increased the table size > TE82882-11 Eric removed rouge instrument SN	For Info	For Info
	20Oct20	- Flex to collect 40 data each tester - is in progress. (Refer to EVALS20033)	For Info	For Info
	24Nov20	- TE82882-8 from 55% to 61.67%; TE82882-11 from 58% to 76.84%; TE82882-13 from 56.67% to 60.29%	For Info	For Info
	24Nov20	- improvement actions identified for each tester. Monitoring is in progress	For Info	For Info
2		<u>PDA Charge Amp PCB start-up/early life failures (refer to Customer Complain slide)</u>		
	16Sep20	- Flex is in progress to raise evaluation form for Waters e-return#133643, for WPPL review and approval	Aldwin/Joel	Closed
	20Sep20	- Refer to EVALS20034. (1) PDA chip - Final Test pass. (2) Charge Amp PCBA - Final Test fail for "Dark Current too low". Further finding - RN3 is faulty.	For Info	For Info
	24Nov20	- FA from Vishay received. Vishay Conclusion: Localized moisture ingress together with applied power over time caused the resistor pattern to deteriorate causing the failure noted.	For Info	For Info

First Pass Yield (SS Data)

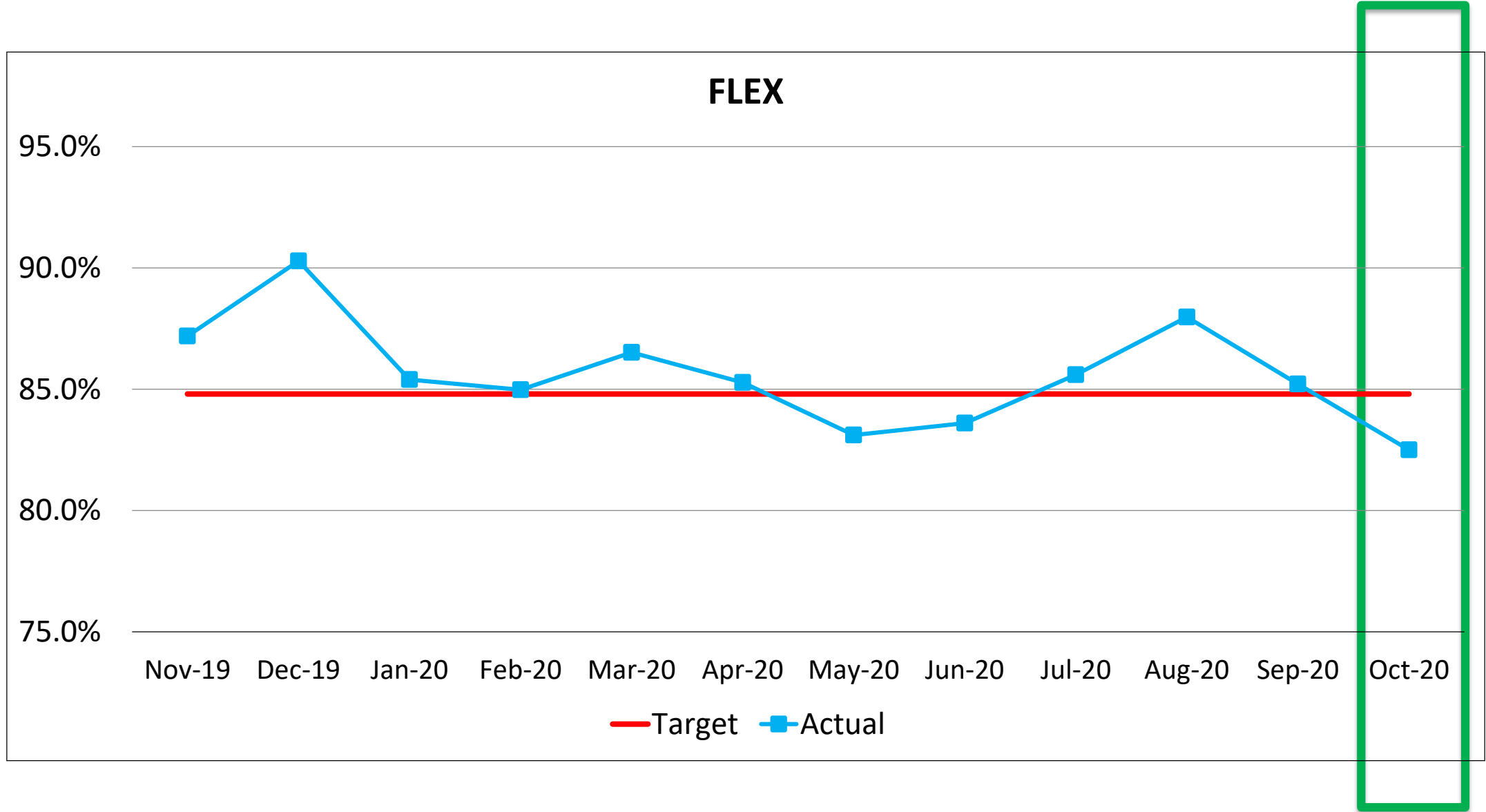
Model
186002998, 186299800,
186015031, 186015032,
186015034 and 186017003
did not meet target

By Instruments

Material Number	Instrument Description	Product Group	Product Class	Target	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
186002487	2489 UV/Visible Detector	Detector	HPLC	92.00%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186002998	2998 Photodiode Array Detector	Detector	HPLC	78.20%	77.8%	66.7%	93.3%	72.7%	60.0%	87.5%	45.5%	40.7%	53.1%	0.0%	40.0%	50.0%
186248900	2489 UV/Visible Detector	Detector	HPLC	99.10%	99.1%	98.9%	95.3%	96.3%	98.7%	100.0%	100.0%	100.0%	99.4%	100.0%	100.0%	99.1%
186299800	2998 Photodiode Array Detector	Detector	HPLC	81.30%	75.5%	74.4%	70.3%	75.9%	85.5%	66.9%	50.8%	87.8%	59.6%	83.7%	61.9%	69.7%
186015031	ACQUITY TUV (with TC)	Detector	UPLC	94.80%	100.0%	87.5%	90.0%	95.1%	95.5%	100.0%	98.9%	94.5%	95.5%	97.8%	97.6%	92.3%
186015032	ACQUITY PDA (with TC)	Detector	UPLC	79.30%	82.1%	85.2%	70.1%	65.5%	69.3%	84.6%	77.4%	65.1%	39.0%	77.6%	58.6%	75.6%
186015033	ACQUITY eλ PDA (with TC)	Detector	UPLC	72.90%	75.9%	68.1%	75.4%	73.4%	66.7%	76.5%	68.4%	45.5%	34.4%	79.4%	80.7%	77.6%
186015034	ACQUITY UPC2 PDA Detector	Detector	UPLC	68.90%	0.0%	100.0%	100.0%	0.0%	100.0%	0.0%	0.0%	0.0%	58.3%	0.0%	0.0%	42.9%
186015053	ACQUITY PDA Detector w/TaperSlit	Detector	UPLC	73.35%	0.0%	100.0%	66.7%	0.0%	80.0%	0.0%	0.0%	0.0%	0.0%	0.0%	50.0%	0.0%
186017002	ACQUITY Arc 2489 UV/Vis Detector	Detector	UPLC	96.90%	100.0%	100.0%	97.5%	90.6%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
186017003	ACQUITY Arc 2998 PDA Detector	Detector	UPLC	81.50%	58.7%	66.7%	91.7%	58.0%	80.0%	62.5%	62.5%	56.3%	50.0%	65.2%	81.3%	68.7%
WAT207000	ASSY, HPLC PUMP, M515	Pump	HPLC	99.40%	94.4%	96.9%	100.0%	100.0%	0.0%	100.0%	100.0%	0.0%	100.0%	100.0%	100.0%	100.0%
186001515	1515 ISOCRATIC HPLC PUMP	Pump	HPLC	100.00%	100.0%	100.0%	100.0%	100.0%	100.0%	90.0%	100.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186001525	1525 BINARY HPLC PUMP	Pump	HPLC	100.00%	100.0%	100.0%	100.0%	100.0%	0.0%	100.0%	100.0%	0.0%	100.0%	100.0%	100.0%	100.0%
186001825	1525 MICRO W/DEGASSER	Pump	HPLC	100.00%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86.50%	89.8%	88.3%	91.3%	89.0%	91.4%	100.0%	88.3%	92.6%	88.6%	90.0%	86.7%	96.5%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	82.00%	84.3%	91.9%	90.1%	90.4%	94.8%	88.5%	86.2%	86.4%	92.8%	89.0%	90.7%	83.7%
186015001	ACQUITY Binary Solvent Manager	BSM	UPLC	50.70%	38.9%	60.0%	23.1%	55.6%	31.6%	36.0%	0.0%	0.0%	44.0%	0.0%	0.0%	55.6%
186015018	ACQUITY QSM	QSM	UPLC	75.00%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	Detector	UPLC	100.00%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186017013	ACQUITY Arc Bio 2998 PDA Detector	Detector	UPLC	84.03%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
186015080	ACQUITY QSM PLUS	QSM Plus	UPLC	52.48%	50.0%	42.9%	55.4%	48.5%	45.7%	54.7%	34.0%	51.9%	60.5%	54.1%	63.1%	53.7%

First Pass Yield (SS Data)

Overall

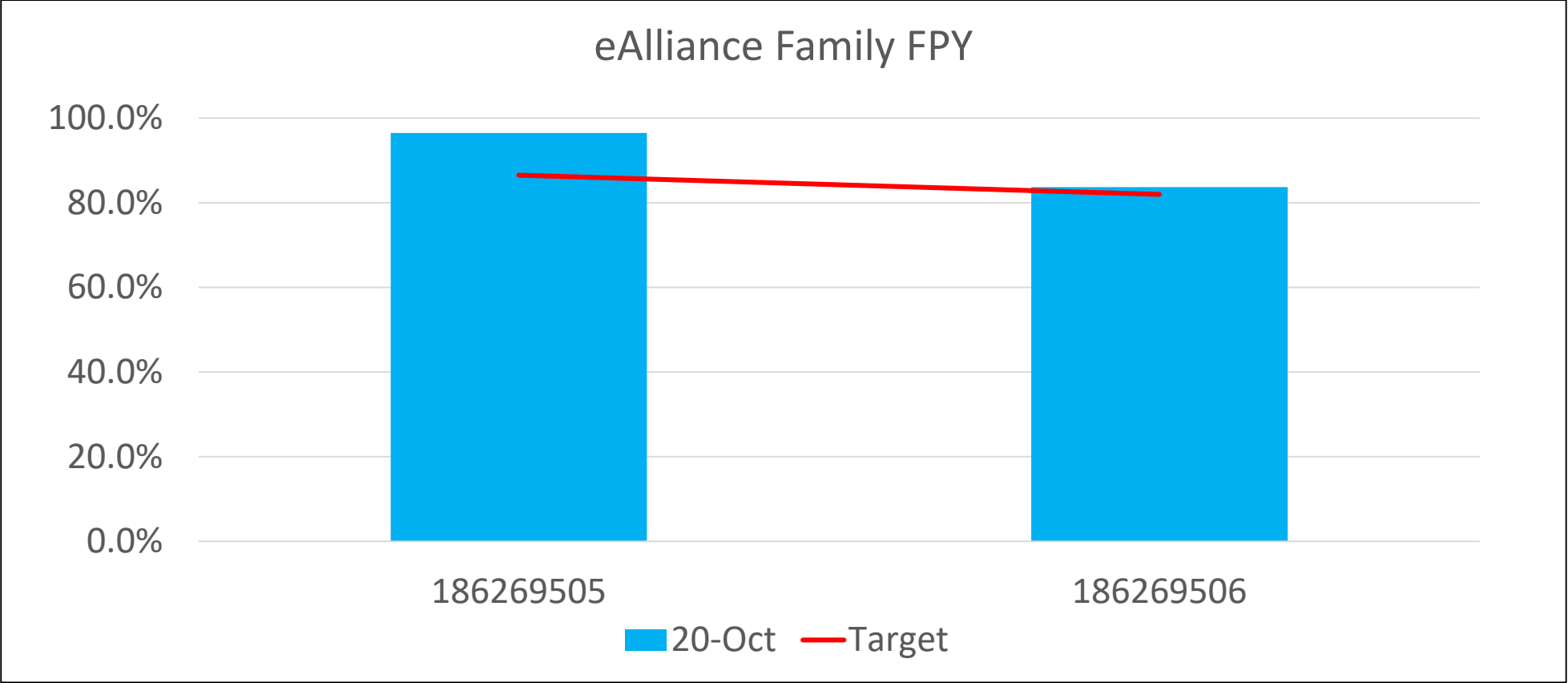


Period	Target	Actual
Nov-19	84.8%	87.2%
Dec-19	84.8%	90.3%
Jan-20	84.8%	85.4%
Feb-20	84.8%	85.0%
Mar-20	84.8%	86.5%
Apr-20	84.8%	85.3%
May-20	84.8%	83.1%
Jun-20	84.8%	83.6%
Jul-20	84.8%	85.6%
Aug-20	84.8%	88.0%
Sep-20	84.8%	85.2%
Oct-20	84.8%	82.5%

NOTE: FPY data shown here are tabulated from SS data.

First Pass Yield (SS Data)

Alliance Family FPY (Oct 2020 data)

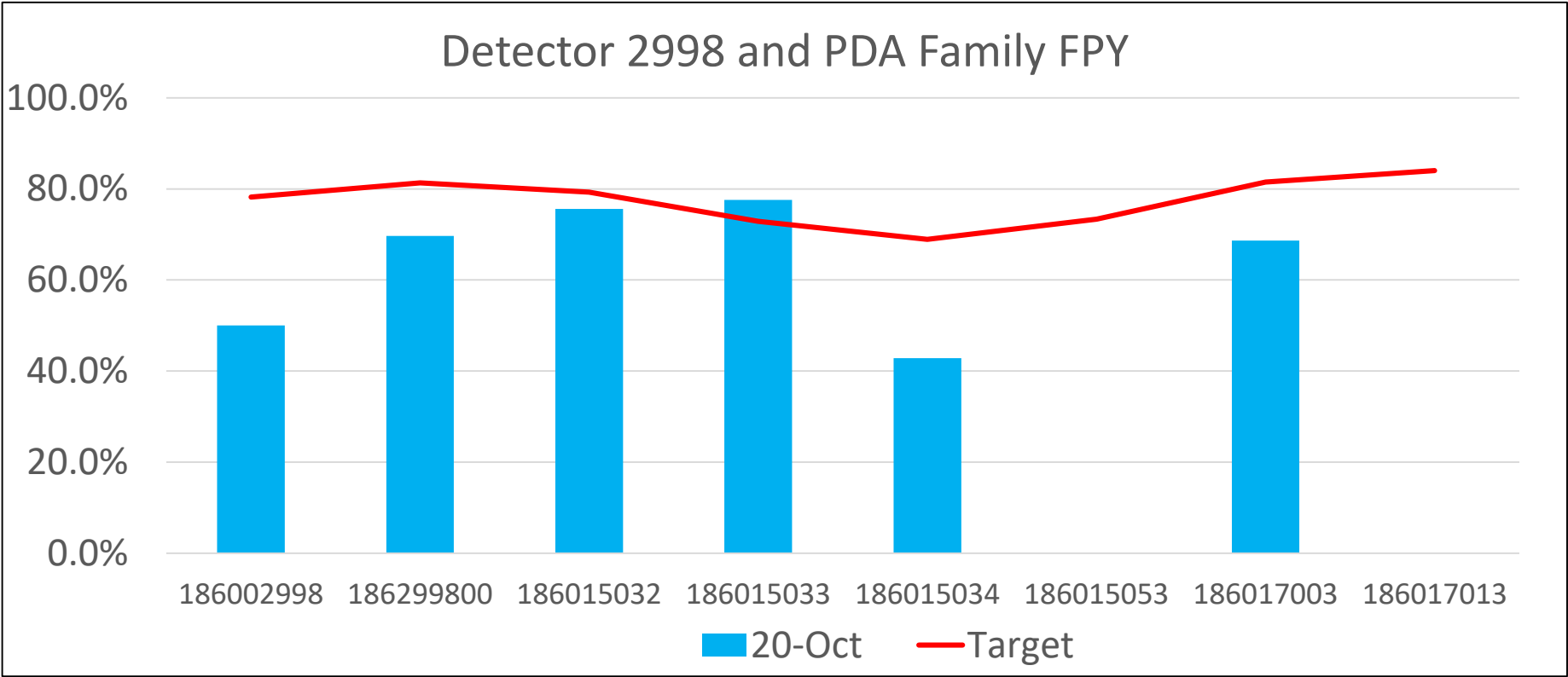


**All model
meet target**

Material Number	Instrument Description	Product Group	Product Class	Target	Oct 20 Qty Tested	Oct 20 Qty Failed	Oct 20 Qty Passed	Oct 20 Yield
186269505	e2695 Separations Module w/o HC	eAlliance	HPLC	86.50%	85	3	82	96.5%
186269506	e2695 Separations Module w/HC	eAlliance	HPLC	82.00%	258	42	216	83.7%

First Pass Yield (SS Data)

Detector 2998 and PDA Family FPY (Oct 2020 data)



Models
186002998, 186299800
186015032,
186015034 and
186017003 did not
meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Oct 20 Qty Tested	Oct 20 Qty Failed	Oct 20 Qty Passed	Oct 20 Yield
186002998	2998 Photodiode Array Detector	2998 and PDA Detector	HPLC	78.20%	26	13	13	50.0%
186299800	2998 Photodiode Array Detector	2998 and PDA Detector	HPLC	81.30%	155	47	108	69.7%
186015032	ACQUITY PDA	2998 and PDA Detector	UPLC	79.30%	127	31	96	75.6%
186015033	ACQUITY eλ PDA	2998 and PDA Detector	UPLC	72.90%	107	24	83	77.6%
186015034	ACQUITY UPC2 PDA Detector	2998 and PDA Detector	UPLC	68.90%	7	4	3	42.9%
186015053	ACQUITY PDA Detector w/TaperSlit	2998 and PDA Detector	UPLC	73.35%	0	0	0	#DIV/0!
186017003	ACQUITY Arc 2998 PDA Detector	2998 and PDA Detector	UPLC	81.50%	67	21	46	68.7%
186017013	ACQUITY Arc Bio 2998 PDA Detector	2998 and PDA Detector	UPLC	84.03%	0	0	0	#DIV/0!

First Pass Yield (SS Data)

186299800 (Oct 2020 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Total Runs			Drift;Total Runs			Noise;Total Run		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
May'20	65	21	32.3%	▲	7	10.8%	▲	2	3.1%	▲
Jun'20	41	1	2.4%	▼	2	4.9%	▼	0	0.0%	—
Jul'20	99	26	26.3%	▲	4	4.0%	▼	1	1.0%	▲
Aug'20	147	15	10.2%	▼	1	0.7%	▼	0	0.0%	—
Sep'20	155	47	30.3%	▲	8	5.2%	▲	2	1.3%	▲
Oct'20	155	28	18.1%	▼	8	5.2%	—	3	1.9%	▲
		Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20
		Communication failure - retest without doing anything		28	Communication failure - retest without doing anything		8	Communication failure - retest without doing anything		3

First Pass Yield (SS Data)

186299800 (Oct 2020 data) – Top 3 failures

		Total Runs	Drift;Total Runs	Noise;Total Run																														
Analysis / Comment	Soft failure, retest and pass. This is considered as event (Re-run test) as part of Final Test process.Production need to perform re-test as per final test procedure																																	
Root Cause / Possible Root Cause	1) Virtual memory space in the Work Station Testers in insufficient. 2) Uninitialized serial number/s in Empower Node. (input from Eric Turner / Hwa Zhen on 04 Feb 2020) 3) Tester configuration conflict of address 4) Damaged Ethernet connectors 5) Suspect tester related. 600 x manual data collection summary result: TE82882-9, 10, 14 showing better yield (9% to 20% of units failed Loss Comm) TE82882-8, 11, 13 showing low yield (43% to 45% of units failed Loss Comm)																																	
Corrective Action	1) Removed old *.DAT files from all testers completed on 26 Dec 2019. 2) Cleared Uninitialized serial number/s in Empower Node before start of test, wef 05 Feb 2020. 3) Removed conflict address on Testers. (Joel Informed HZL and Eric on 06 Mar 2020). 4) Replaced all damaged connector on TE82882-8 (pos 1 to 4), TE82882-9 (pos 2 & 3), TE82882-14 (pos 2, 3 & 4) 5) Submitted completed data to Waters for further analysis (refer to EVALS20015) Remarks: Waters acknowledged its impact to production yield and agree Flex processes is not the cause, WPPL unable to exclude the yield loss as this affect data integrity in reporting. Still, Waters will work with Flex to mitigate this impact on Flex overall performance. 6) Eric Turner made change / adjustment to below and continual feedback is still on-going.: > TE82882-8 Eric increased the table size > TE82882-11 Eric removed rouge instrument SN 6. Data collection update <table><tr><th colspan="5">Manual Data Collection from after Eric Turner suggestion Start: 13 Oct 2020 (EVALS20033)</th></tr><tr><th>TE82882</th><th>TE82882-8</th><th>TE82882-11</th><th>TE82882-13</th><th>Total</th></tr><tr><td>TESTED</td><td>53</td><td>63</td><td>50</td><td>163</td></tr><tr><td>LOSS COMM</td><td>13</td><td>14</td><td>18</td><td>45</td></tr><tr><td>FPY %</td><td>74.00%</td><td>77.78%</td><td>64.00%</td><td>72.39%</td></tr><tr><td>Baseline (EVALS20015)</td><td>55.00%</td><td>58.00%</td><td>57.00%</td><td>56.67%</td></tr></table> TE82882-8 : Replacement of Relay Box (Measurement and Computing) and data collection - 30 Nov 2020 TE82882-11 : Continue monitoring TE82882-13 : Replaced the ethernet header LAN cable for position 3 - Continue monitoring				Manual Data Collection from after Eric Turner suggestion Start: 13 Oct 2020 (EVALS20033)					TE82882	TE82882-8	TE82882-11	TE82882-13	Total	TESTED	53	63	50	163	LOSS COMM	13	14	18	45	FPY %	74.00%	77.78%	64.00%	72.39%	Baseline (EVALS20015)	55.00%	58.00%	57.00%	56.67%
Manual Data Collection from after Eric Turner suggestion Start: 13 Oct 2020 (EVALS20033)																																		
TE82882	TE82882-8	TE82882-11	TE82882-13	Total																														
TESTED	53	63	50	163																														
LOSS COMM	13	14	18	45																														
FPY %	74.00%	77.78%	64.00%	72.39%																														
Baseline (EVALS20015)	55.00%	58.00%	57.00%	56.67%																														
Effectiveness	1) Based on Jan 2020 data, no significant improvement. Result: from 20% to 18% failure 2) Based on 06 Feb to 28 Feb 2020 data, no improvement. Result: from 18% to 17.5% failure 3) Base on 01 Mar to 30 Mar 2020 data, no significant improvement. Result: from 17.5% to 13.95% 4) Base on 01 Apr to 30 Apr 2020 data, no improvement. Result: from 13.95% to 20.59%, 5) Monitoring in progress for 3 station TE82882-8, 11 and 13 (using EVALS20033 v00 - Closed) 6) Monitoring in progress for 3 station TE82882-8, 11 and 13 (using EVALS20033 v01 - In-progress)																																	

First Pass Yield (SS Data)

186002998 (Oct 2020 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Total Runs;			Noise;Final Noise			Drift;Total Runs		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
Apr'20	8	1	12.5%		0	0.0%		0	0.0%	
May'20	11	4	36.4%		0	0.0%		1	9.1%	
Jun'20	27	5	18.5%		1	3.7%		0	0.0%	
Jul'20	32	11	34.4%		1	3.1%		0	0.0%	
Aug'20	1	0	0.0%		0	0.0%		0	0.0%	
Sep'20	5	3	60.0%		0	0.0%		0	0.0%	
Oct'20	26	10	38.5%		2	7.7%		1	3.8%	
		Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20
		Communication failure - retest without doing anything		10	Noise failure - retest without doing anything		2	Communication failure - retest without doing anything		1

First Pass Yield (SS Data)

186002998 (Oct 2020 data) – Top 3 failures

		Top 1	Top 2	Top 3
		Total Runs;	Noise;Final Noise	Drift;Total Runs
Analysis / Comment	Refer to slide for 186299800		Random failure, retest and pass it is allowed to verify after retest and the UUT pass	Refer to slide for 186299800
Root Cause / Possible Root Cause			Random failure. Low priority to work on this as the failure qty is low.	
Corrective Action			Low priority to work on	
Effectiveness			NA	

First Pass Yield (SS Data)

186015032 (Oct 2020 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Total Runs			Leak Detector Test;			Noise;Final Noise		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
May'20	31	1	3.2%	▲	0	0.0%	—	0	0.0%	—
Jun'20	83	7	8.4%	▲	4	4.8%	▲	2	2.4%	▲
Jul'20	41	12	29.3%	▲	1	2.4%	▼	0	0.0%	—
Aug'20	49	5	10.2%	▼	2	4.1%	▲	0	0.0%	—
Sep'20	70	16	22.9%	▲	2	2.9%	▼	0	0.0%	—
Oct'20	127	20	15.7%	▼	4	3.1%	▲	2	1.6%	▲
		Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20
		Communication failure - Retest without doing anything		20	Retest after re-insert interface cable		4	Noise failure - Retest without doing anything		2

First Pass Yield (SS Data)

186015032 (Oct 2020 data) – Top 3 failures

		Top 1	Top 2	Top 3
		Total Runs	Leak Detector Test;	Noise;Final Noise
Analysis / Comment	Refer to slide for 186299800		Upon Leak Detection Test failure, cycle Power and re-inserted the interface cable and retest UUT Passed. No replacement of parts involved.	Tester automatically run Noise test for 5 x cycles. Upon Noise test failure, Cycle Power and retest without doing anything, UUT Pass. No replacement of parts involved.
Root Cause / Possible Root Cause			Visual insprection of the interface cable does not show wear and tear. However, team proposed to replaced the interface cable.	Random failure. Low priority to work on this as the failure qty is low.
Corrective Action			Interface cable replaced 20 Nov 2020	Low priority to work on
Effectiveness			Continue monitoring	NA

First Pass Yield (SS Data)

186017003 (Oct 2020 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Total Runs;			Drift;Final Drift			Drift;Total Runs		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
May'20	16	4	25.0%		0	0.0%		2	12.5%	
Jun'20	16	5	31.3%		1	6.3%		0	0.0%	
Jul'20	32	12	37.5%		1	3.1%		1	3.1%	
Aug'20	23	4	17.4%		2	8.7%		1	4.3%	
Sep'20	16	3	18.8%		0	0.0%		0	0.0%	
Oct'20	67	17	25.4%		2	3.0%		1	1.5%	
		Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20
		Communication failure - retest without doing anything		17	Communication failure - retest without doing anything		2	Communication failure - retest without doing anything		1

First Pass Yield (SS Data)

186017003 (Oct 2020 data) – Top 3 failures

		Top 1	Top 2	Top 3
		Total Runs;	Drift;Final Drift	Drift;Total Runs
Analysis / Comment	Refer to slide for 186299800		Random failure, retest and pass it is allowed to verify after retest and the UUT pass	Refer to slide for 186299800
Root Cause / Possible Root Cause			Random failure. Low priority to work on this as the failure qty is low.	
Corrective Action			Low priority to work onEffectiveness1	
Effectiveness			NA	

First Pass Yield (SS Data)

186015034 (Oct 2020 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Total Runs			NA			NA		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
May'20	0	0	0.0%		-	-	-	-	-	-
Jun'20	0	0	0.0%		-	-	-	-	-	-
Jul'20	12	1	8.3%		-	-	-	-	-	-
Aug'20	0	0	#DIV/0!		-	-	-	-	-	-
Sep'20	0	0	#DIV/0!		-	-	-	-	-	-
Oct'20	7	4	57.1%		-	-	-	-	-	-
		Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20
		Total Run- Retest without doing anything		4	-		-	-		-

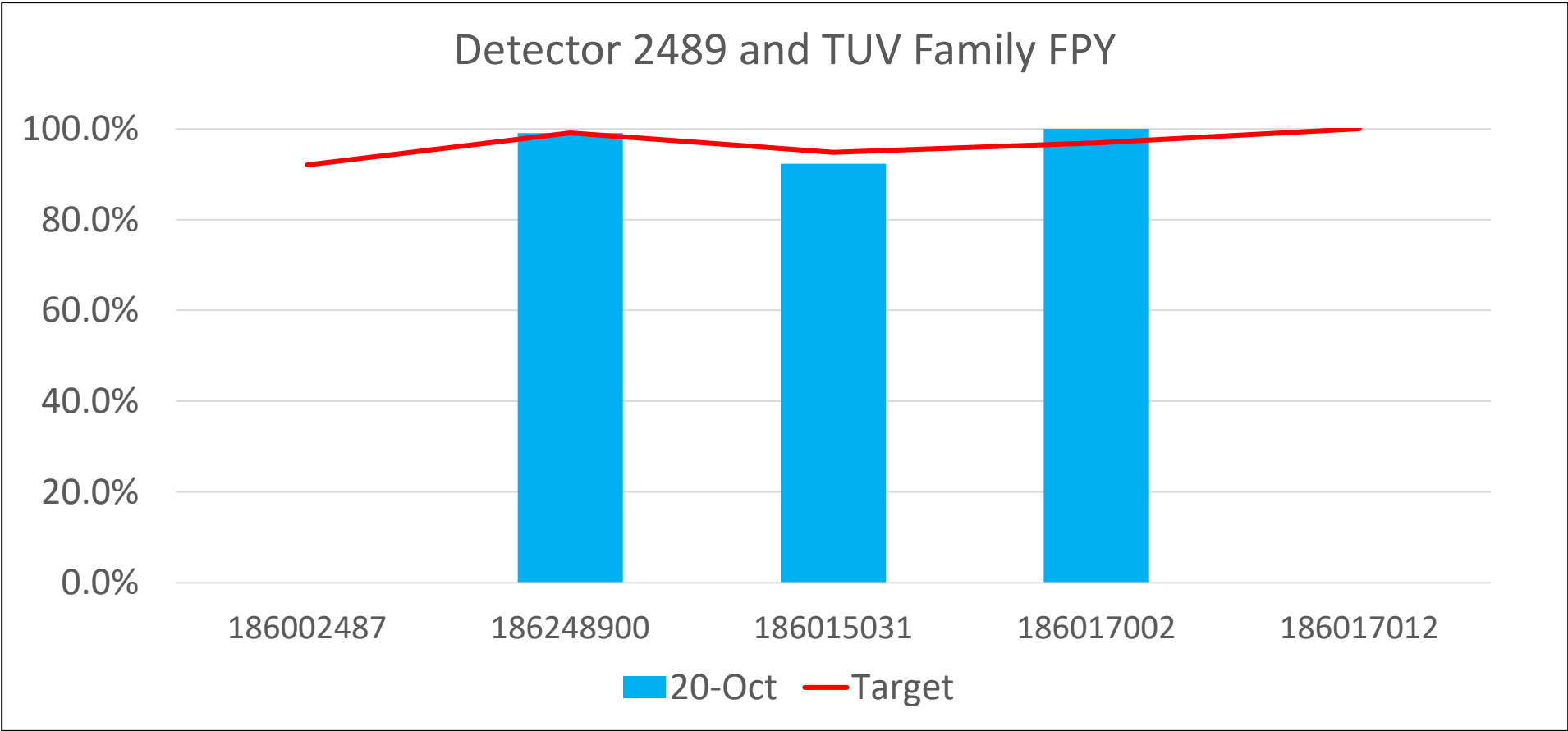
First Pass Yield (SS Data)

186015034 (Oct 2020 data) – Top 3 failures

		Top 1	Top 2	Top 3
		Total Runs	NA	NA
Analysis / Comment	Refer to slide for 186299800		-	-
Root Cause / Possible Root Cause			-	-
Corrective Action			-	-
Effectiveness			-	-

First Pass Yield (SS Data)

Detector 2489 and TUV Family FPY (Oct 2020 data)



**Model
186015031
did not meet
target**

Material Number	Instrument Description	Product Group	Product Class	Target	Oct 20 Qty Tested	Oct 20 Qty Failed	Oct 20 Qty Passed	Oct 20 Yield
186002487	2489 UV/Visible Detector	2489 and TUV Detector	HPLC	92.00%	0	0	0	#DIV/0!
186248900	2489 UV/Visible Detector	2489 and TUV Detector	HPLC	99.10%	213	2	211	99.1%
186015031	ACQUITY TUV	2489 and TUV Detector	UPLC	94.80%	104	8	96	92.3%
186017002	ACQUITY Arc 2489 UV/Vis Detector	2489 and TUV Detector	UPLC	96.90%	53	0	53	100.0%
186017012	ACQUITY Arc Bio 2489 UV/Vis Detector	2489 and TUV Detector	UPLC	100.00%	0	0	0	#DIV/0!

First Pass Yield (SS Data)

186015031 (Oct 2020 data) – Top 3 failures

		Top 1			Top 2			Top 3		
		Noise Test;			Dual Noise Test;			NA		
Mth	Qty Tested	Qty Failed	% Failed		Qty Failed	% Failed		Qty Failed	% Failed	
May'20	89	1	1.1%		0	0.0%		-	-	-
Jun'20	55	3	5.5%		0	0.0%		-	-	-
Jul'20	44	2	4.5%		0	0.0%		-	-	-
Aug'20	89	2	2.2%		0	0.0%		-	-	-
Sep'20	123	3	2.4%		0	0.0%		-	-	-
Oct'20	104	6	5.8%		2	1.9%		-	-	-
		Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20	Debug Breakdown / Finding		Oct'20
		Retest witout doing anything		6	Retest witout doing anything		2	-		-

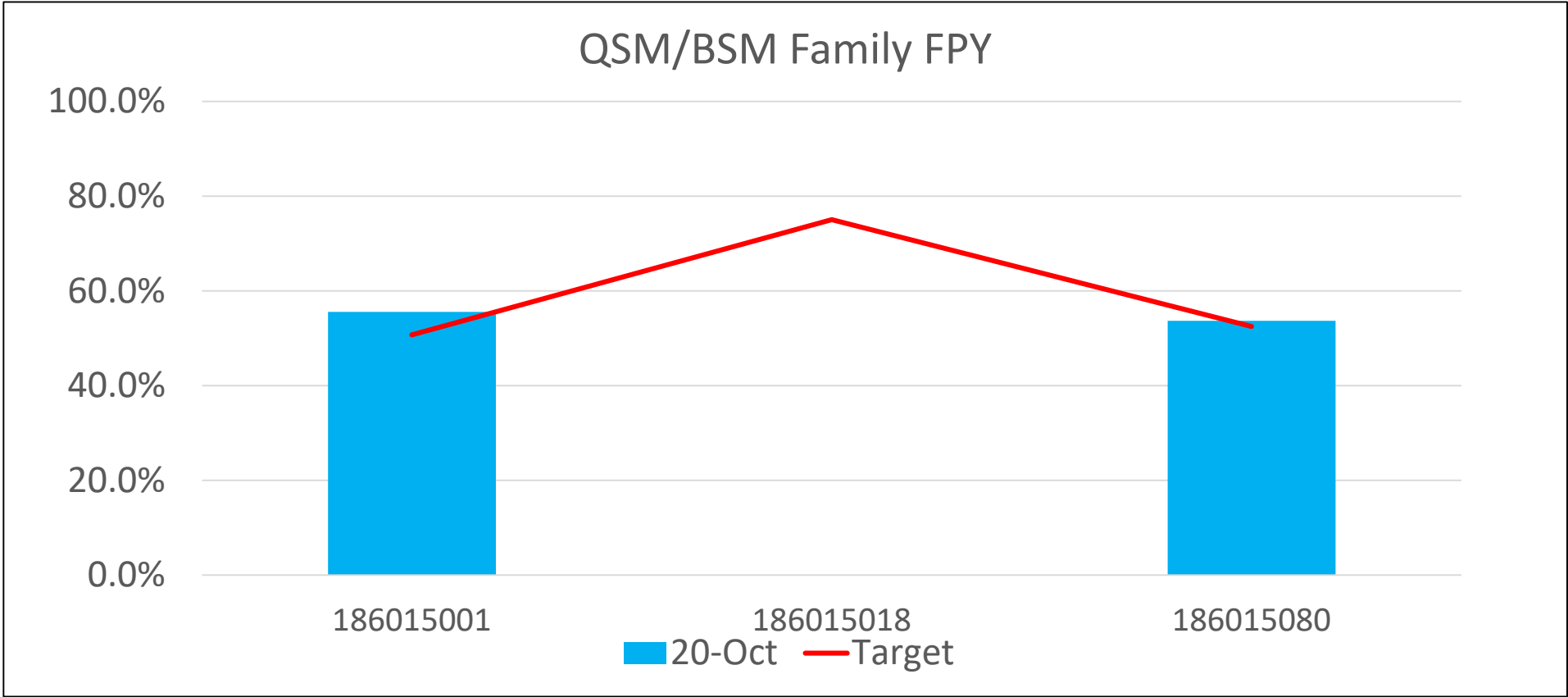
First Pass Yield (SS Data)

186015031 (Oct 2020 data) – Top 3 failures

		Top 1	Top 2	Top 3
		Noise Test;	Dual Noise Test;	NA
Analysis / Comment		Tester automatically run Noise test for 5 x cycles. Upon Noise test failure, Cycle Power and retest without doing anything, UUT Pass. No replacement of parts involved.	Tester automatically run Dual Noise test for 99x cycles. Tester operator aborted test. Cycle Power and retest without doing anything.	-
Root Cause / Possible Root Cause		Random failure. Low priority to work on this as the failure qty is low.	Random failure. Low priority to work on this as the failure qty is low.	-
Corrective Action		Low priority to work on	Low priority to work on	-
Effectiveness		NA	NA	-

First Pass Yield (SS Data)

QSM/BSM Family FPY (Oct 2020 data)

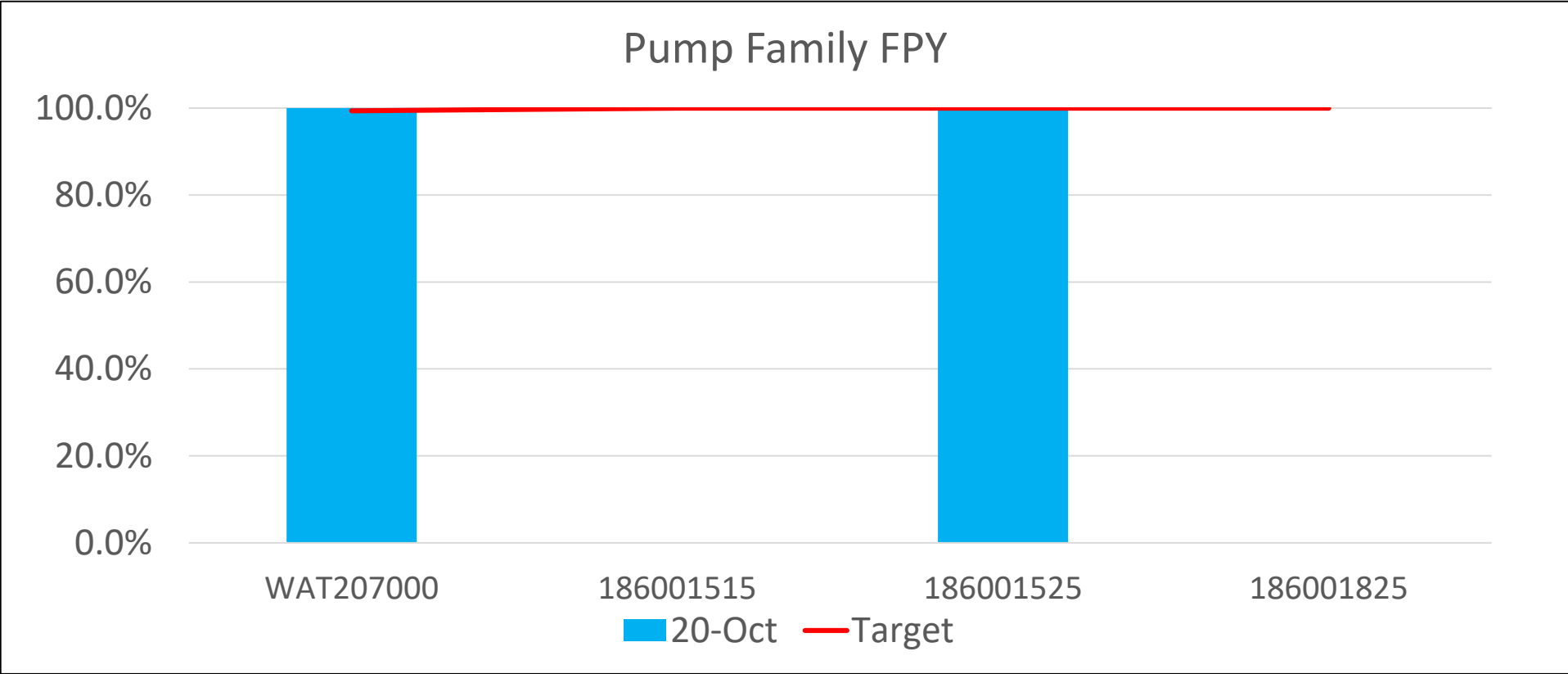


All model
meet target

Material Number	Instrument Description	Product Group	Product Class	Target	Oct 20 Qty Tested	Oct 20 Qty Failed	Oct 20 Qty Passed	Oct 20 Yield
186015001	ACQUITY Binary Solvent Manager	BSM	UPLC	50.70%	18	8	10	55.6%
186015018	ACQUITY QSM	QSM	UPLC	75.00%	0	0	0	#DIV/0!
186015080	ACQUITY QSM Plus	QSM Plus	UPLC	52.48%	231	107	124	53.7%

First Pass Yield (SS Data)

Pump Family FPY (Oct 2020 data)



Material Number	Instrument Description	Product Group	Product Class	Target	Oct 20 Qty Tested	Oct 20 Qty Failed	Oct 20 Qty Passed	Oct 20 Yield
WAT207000	ASSY, HPLC PUMP, M515	Pump	HPLC	99.40%	24	0	24	100.0%
186001515	1515 ISOCRATIC HPLC PUMP	Pump	HPLC	100.00%	0	0	0	#DIV/0!
186001525	1525 BINARY HPLC PUMP	Pump	HPLC	100.00%	16	0	16	100.0%
186001825	1525 MICRO W/DEGASSER	Pump	HPLC	100.00%	0	0	0	#DIV/0!

TMD Updates

TMD summary

TMD Tracker 2018		
Total TMD Received	No of TMD closed	No of TMD open
28	27	1

TMD Tracker 2019		
Total TMD Received	No of TMD closed	No of TMD open
18	18	0

TMD Tracker 2020		
Total TMD Received	No of TMD closed	No of TMD open
13	8	5

TMD – OPEN

Originator: Joe Gately	Date: 11-Mar-2020	TMD #: TMD010508	v 04
Lab Office: AKX	Notify: Kris Bujold, Monica Collins,	Requester: Ken Voisine	
P/N(s): See below	P/N See Below Desc.:		
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 31-Dec-2020	Expiration Detail: N/A	
Risk Assessor: Joe Gately	TMD Category: Nonconforming Part		
Reason for Deviation <i>(describe why deviation is needed):</i> The drawings for the following list of materials contains a requirement that the packaging of the part to contain verbiage "WATERS CRITICAL CLEAN per 735001035" be on their label to assist in identification' per design spec 735001035 Section 7.2. Currently these parts do not comply to this labeling requirement. This TMD will allow the receipt of these parts until such time as the labeling can be added to the packaging. This TMD is being updated to add three parts requested by SQE. No other changes are included.			
Implementation Plan <i>(describe who, when, how of implementation):</i> This TMD will be implemented by the incoming inspection and procurement teams and applies to Milford and the contract manufacturers CEI, Venture/GES and Flextronics. Waters purchasing and Supplier Quality will need to work with the above suppliers to implement the specified labeling "WATERS CRITICAL CLEAN per 735001035". The duration of this TMD is to allow the supply chain time to implement the proper labeling per the 735001035 specification.			

Status : active

TMD - OPEN

Originator: Joe Gately	Date: 07-Oct-2020	TMD #: TMD010766	v 02
Lab Office: AKA	Notify: See Implementaion Plan	Requester: Randy Weaner	
P/N(s): See Appendix A	P/N See Appendix A Desc.:		
Expiration Type: ☒ Date <i>or</i> ☐ Qty/Lot	Expiration Date: 30-Apr-2021	Expiration Detail: N/A	
Risk Assessor: Ethan Peloquin	TMD Category: Design Change		
Reason for Deviation (<i>describe why deviation is needed</i>): Pre implement ECO 9236253. Waters EC Rep has changed from Wilmslow, UK to Etten-Leur, The Netherlands due to the withdrawal of the United Kingdom from the European Union (Brexit). Reference page 22 of Finished Product Labeling Requirements document 730000504. The Document shows the change of address of the EC Rep after March 29, 2019 for IVD instruments. All other instruments will have the EC Rep silkscreen removed.			
Implementation Plan (<i>describe who, when, how of implementation</i>): Utilize this TMD to manage work orders to pre implement ECO 9236253. Over label the silk screened EC Rep with label 615005253. For the TCM/PCM models (PN 186002441 and 186002449) two labels will be required. Verify the EC Rep is covered by the blank label(s) via a label verification process. Management of this TMD will be defined and managed by the local quality organization at the point of manufacture. This TMD will impact Milford manufacturing as well as the contract manufacturers in Singapore. Individuals to be notified: Paul Castano Luis Orosco Michael Doyle Ethan Peloquin Kah Chin Tan Eugene Tan Wan Jing Loh Jen Chen			

Status : active

TMD - OPEN

Originator: Leo Bates	Date: 23-Mar-2020	TMD #: TMD010809	v 00
Lab Office: MAC	Notify: Tony Shieh, Ethan Peloguin	Requester: Leo Bates	
P/N(s): 205001691		P/N Kit, Vendor Color Control Panels Desc.:	
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 31-DEC-2020	Expiration Detail: N/A	
Risk Assessor: Peter Kirby	TMD Category: Nonconforming Process		
Reason for Deviation <i>(describe why deviation is needed)</i>: This deviation is needed because the Light Grey Color Panel 410004392 the AcQuity Light Blue Color Panel 410004229, AcQuity Dark Blue Color Panel 410004230 & Titanium Grey Color Panel 410004231 that make P/N 205001691 will expire March 27,2020. Waters has 37 paint sample kits in stock to send out to supplies. These samples will need to be inspected to ensure they meet specification and a new expiration date of two years will be put on all labeling. This TMD will allow the proper time for Waters to correct the process for the issuing of these paint samples to the suppliers.			
Implementation Plan <i>(describe who, when, how of implementation)</i>: All 37 paint kits P/N 205001691 will be measured in the Milford Incoming material Audit (IMA) group per waters Engineering group standard for these paint kits. The actuals for each kit will be documented and stored on the IMA secure server. All kits will be serialized and identified to match up with the measured reading from IMA. All kits will be given a new 2year expiration date and sent to the suppliers required to have these kits for their process. Paint chips can be used for the evaluation of Waters product. Supplier Quality Engineering from Milford and Singapore will be responsible for notifying their respective suppliers of this deviation.			

Status : active

TMD - OPEN

Originator: Julie McLarnon	Date: 10-Aug-2020	TMD #: TMD010795	v 03
Lab Office: SP1	Notify: Tony Shieh	Requester: Ethan Peloquin	
P/N(s): 735002580	P/N Color Specification Titanium Grey Desc.:		
Expiration Type: ☐ Date <i>or</i> ☒ Qty/Lot	Expiration Date: N/A	Expiration Detail: Batch 19281	
Risk Assessor: Ethan Peloquin	TMD Category: Use Up Stock		
Reason for Deviation (<i>describe why deviation is needed</i>): It was identified on 21Oct2019 that paint batch 19281 for titanium gray was accepted for delta E reading of 1.31. Per color specification Titanium Grey, Doc # 735002580, allowable Delta E range is 0-0.80 and marginal range is 0.80-1.20, acceptable with a visual confirmation to the visual master. Paint batch 19281 for titanium gray was also accepted for glossiness G reading of 4.3. Per color specification Titanium Grey, Doc # 735002580, acceptable glossiness G range is 6-9.			
Implementation Plan (<i>describe who, when, how of implementation</i>): Upon Approval of the TMD: The paint batch 19281 will be allowed to be applied to Waters parts (listed above). Paint batch 19281 is not to be mixed with future batches. Paint applicator will be instructed to visually verify color in relation to mating parts and against color controlled panel 410004231 supplied by Waters. Paint applicator will be instructed to visually verify gloss in relation to mating parts and against Munsell Card supplied by Waters. Incoming Inspectors at contract manufacturers shall make a visual appearance judgement for color in accordance with 730000842 Corporate Color Policies and Practices, Sections 6.16 and 6.17, against Munsell card supplied by Waters, made using color controlled panel 410004231. Incoming Inspectors at contract manufacturers to do sampling visual check of the part received (279002588) against Munsell color chip, no spectrometer measurement is required for the TMD parts'. Control panel shall be stored in provided envelopes and in a secure location when not in use. Panels are to be handled with latex glove or applicable substitute to minimize color deterioration. If product fails visual appearance judgement, parts shall be segregated into nonconforming product area and scrapped to Waters account. Available upon request. For parts that accepted, not required to trace the part usage to the Instrument Level.			

Status : active
 Expect to consume this batch of paint 28 Feb 2021.

TMD - OPEN

Originator: Bob Lincoln	Date: 16-Sep-2020	TMD #: TMD010869	v 00
Lab Office: SPE	Notify: See Implementation Plan	Requester: Bryan Deguire	
P/N(s): 410001398	P/N INSULATOR, BATTERY, MYLAR Desc.:		
Expiration Type: ☐ Date or ☒ Qty/Lot	Expiration Date: N/A	Expiration Detail: Single purchase 10,000 pcs	
Risk Assessor: Bob Lincoln	TMD Category: Material Shortage		
Reason for Deviation <i>(describe why deviation is needed):</i> The reason for this deviation is that the MOQ (Minimum Order Quantity) for 410001398 is now 1.5 million pieces, which at annual usage of 3,200 pieces, is approximately a 450-year supply. Cost and inventory make this a prohibitive condition - \$150,000 order instead of about \$320 per year. A replacement battery insulator with a reasonable MOQ must be substituted as soon as possible, as inventory will run out this month.			
Implementation Plan <i>(describe who, when, how of implementation):</i> Contract Manufacturer (Flextronics) is to purchase 10,000 pieces of 336000333 and phase in its use when they run out of 410001398 battery insulator this month. Flextronics will be copied on this TMD and ensure that their operators are made aware of the substitution. This lot size will last until a future ECR changes the BOM of the affected board. No process change or rework is necessary. This TMD to be copied to the following personnel at Waters and at Flextronics: Dave Reed Dave_Reed@waters.com Principal Commodity Manager Bethany Lim Bethany_Lim@waters.com Procurement Engineer Kho Chun Wei ChunWei.Kho@flex.com Program Administrator			

Status : pend

Based on Senai inventory, to phase in the new Batt Insulator in Apr 2021.

TMD - OPEN

Originator: Shaynee Lim		Date: 06-Oct-2020	TD # TMD010882	v 00
Requester: Shaynee Lim		Risk Assessor: Edward Jackson		
P/N(s) : (or Doc. No.) 186015001	P/N (or Doc.) Description: Acquity UPLC Binary Solvent Mgr			
ECR/ECO Number(s): N/A	TD Type: TMD		TD Category: Material Shortage	
Lab Office: SP2	Lab Office Details(if applicable): N/A			
Expiration Type: ☒ Date or ☐ Qty/Lot	Expiration Date: 08-Jan-2021	Expiration Detail:		
Reason for Deviation <i>(describe why deviation is needed):</i> The new transducer P/N 279010881 TRANSDUCER, PRESS, 15.5KSI, V, PUMP HEAD "P/N 279010881" used in 186015001 Acquity UPLC Binary Solvent Manager (BSM) fails pressure ripple test spec per TSP 735002010 Rev P Step 83 and step 86 when running at a 2ml/min flow rate during ACQUITY BSM PUMP AUTOMATED FINAL TEST. This issue only affects the 186015001 model. This TMD is to allow Flex to use P/N 279000881 for manufacturing of 186015001 Acquity UPLC BSM in place of P/N 279010881.				
Implementation Plan <i>(describe who, when, how of implementation):</i> 1. Flex to use the P/N 279000881 for 186015001 Acquity UPLC BSM for ASP 279000886 ASP ASSY, ACTUATOR, UPLC and test per 735002010 ACQUITY BSM PUMP AUTOMATED FINAL TEST. 2. Upon passing final test, Flex shall pack and ship the units per current practice. 3. Flex to on-hold and report to Waters for any failed units related or suspect related to Transducer. 4. Flex to provide the start and end BSM instrument S/N under this TMD.				

Status : active

TMD - OPEN

Originator: Matt Franklin		Date: 14-Oct-2020	TD # TMD010885	v 00
Requester: Matt Franklin		Risk Assessor: Matt Franklin		
P/N(s) : (or Doc. No.)	See Below	P/N (or Doc.) Description:	See Below	
ECR/ECO Number(s):	9237907	TD Type: TMD	TD Category: Nonconforming Process	
Lab Office:	AKU	Lab Office Details(if applicable):	N/A	
Expiration Type:	☒ Date or ☐ Qty/Lot	Expiration Date:	02-Dec-2020	Expiration Detail: N/A
Reason for Deviation <i>(describe why deviation is needed):</i> The 515, 1515, 1525 pumps do not specify a torque spec on the support plate screws and the pump head screws. A torque spec should be specified to ensure manufacturing practices can meet the pumps performance needs.				
Implementation Plan <i>(describe who, when, how of implementation):</i> This TMD impacts Singapore production only. Upon approval of this TMD Singapore production will implement the new torque spec as described in Deviation Description.				

Status : active

1st SN

- PN: 186001525
- (SN: L2025P014A),

- PN: WAT20700
- (SN: L20515020A),

- PN: 186001515
- (SN: L2015P002A)

ECO Tracker Updates 2018 & 2019

ECO Tracker 2018					
Total ECR/ECO Received	No. of ECO Closed	No. of ECO Open	Remarks	Waters ECO Effective Date	Flex ECO Effective Date (Update: 24-Nov-20)
169	167	2	2: Awaiting effective date	ECO9219022: Effective date 22-Aug-2018 ECO9222766: Effective date 01-Oct-2019	ECO9219022: Awaiting effective date-TBA: 68pcs horizon excess ECO9222766: Awaiting effective date-TBA: 03pcs horizon excess
ECO Tracker 2019					
Total ECR/ECO Received	No. of ECO Closed	No. of ECO Open	Remarks	Waters ECO Effective Date	Flex ECO Effective Date (Update: 24-Nov-20)
97	93	4	1: Awaiting effective date 3: Future effective date	ECO9227566: Effective date 31-Jan-2019 ECO9227997: Effective date 13-Jun-2019 ECO9227139: Effective date 12-Aug-2020 ECO9232041: Effective date 01-Jul-2020	ECO9227566: Awaiting effective date TBA: 68pcs horizon excess ECO9227997: Future Effective date 24-Dec-2020 ECO9227139: Future effective date 07-Apr-2021 ECO9232041: Future effective date 28-Jun-2022

ECO Tracker Updates 2020

ECO Tracker 2020					
Total ECR/ECO Received	No. of ECO Closed	No. of ECO Open	Remarks	Waters ECO Effective Date	Flex ECO Effective Date (Update: 16-Nov-20)
87	55	32	17: Future effective date 2: Pending Future effective date 4: Awaiting effective date 9: ECO yet to be received	ECO9235885: Effective date: 16-Nov-20 ECO9236966: Effective date: 09-Nov-20 ECO9235357: Effective date: 27-Oct-20 ECO9231082: Effective date: 20-Sep-20 ECO9238351: Effective date: 06-Nov-20 ECO9233497: Effective date: 16-Nov-20 ECO9233327: Effective date: 18-Nov-20 ECO9232680: Effective date: 29-Apr-20 ECO9235495: Effective date: 21-Jan-21 ECO9235493: Effective date: 21-Jan-21 ECO9234970: Effective date: 21-Jan-21 ECO9236253: Effective date: 08-Apr-21 ECO9236915: Effective date: 04-Nov-20 ECO9236200: Effective date: 09-Sep-20 ECO9236999: Effective date: 23-Dec-20 ECO9237272: Effective date: 13-Jan-21 ECO9237643: Effective date: 18-Nov-20 ECO9234770: Effective date: 03-Apr-20 ECO9236181: Effective date: 27-Jul-20 ECO9232012: Awaiting effective date ECO9238344: Awaiting effective date ECO9210233: Awaiting effective date ECO9220956: Awaiting effective date	ECO9235885: Future effective date: 30-Nov-20 ECO9236966: Future effective date: 30-Nov-20 ECO9235357: Future effective date: 30-Nov-20 ECO9231082: Future effective date: 30-Nov-20 ECO9238351: Future effective date: 30-Nov-20 ECO9233497: Future effective date: 01-Mar-21 ECO9233327: Future effective date: 26-May-21 ECO9232680: Future effective date: 07-Apr-21 ECO9235495: Future effective date: 21-Jan -21 ECO9235493: Future effective date: 21-Jan -21 ECO9234970: Future effective date: 21-Jan -21 ECO9236253: Future effective date: 20-Jan-21 ECO9236915: Future effective date: 10-Mar -21 ECO9236200: Future effective date: 26-Nov-20 ECO9236999: Future effective date: 03-Feb-21 ECO9237272: Future effective date: 13-Jan -21 ECO9237643: Future effective date: 02-Dec-20 ECO9234770: Future effective date: Pending ECO9236181: Future effective date: Pending ECO9232012: Awaiting effective date ECO9238344: Awaiting effective date ECO9210233: Awaiting effective date ECO9220956: Awaiting effective date

Competency Check Update

In Progress

Complete

Product Family	Jan '20	Feb '20	Mar '20	Apr '20	May '20	Jun '20	Jul '20	Aug '20	Sep '20	Oct '20	Nov '20	Dec '20
Quarterly Competency Check by Flex		186001515		186269506	186269506		186015080	186015080			186015031	
Monthly Competency check by Waters							* 186001515	186269506	186015031	186015001	186269505	TBD

* Monthly competency check by Waters initiated in addition to Flex’s quarterly check in Jul 20

Observations	Oct '20	Remarks	Status
Sequence not followed	0	NA	
Labelling & Identification	0	NA	
ASP/TSP Update required	1	279003870 Rev D page 61, the “OPER 8.1” is carried out at a different station which is the cutting of the tube. To update Flex work instructions to add note of tubing that are pre-cut at different station prior to build.	In-progress
Wear & Tear	0	NA	
5S	2	1. The glue gun was placed in the wrong compartment. It was not attended to. After informing them, it was rectified immediately. 2. The solvent waste carboy was unattended and was in the middle of the pathway. After informing them, it was rectified immediately.	Closed



Training Updates

Training Matrix Update for Oct'20

Sno	Family	Training Status	Workstations
1	Alliance	1 HC under OJT training	Hipot & Final test (x1)
2	BSM/QSM+	3 HC under OJT training	Main Chassis Assy (x1) Actuator Assy & Test (x2)
3	Detectors (Clean Room)	Nil	NA
4	Detectors (Non-Clean room)	3 HC under OJT training	Optics Bench & Main Chassis Assy (x2) Hipot & Final test (x1)
5	Pumps	Nil	NA



Microsoft Excel
Worksheet

Test Engineering

TESTER DASHBOARD – submitted separately every end of the month

Downtime Summary								
Start Date	End Date	Dowtime (Day:Hour :Min)	Tester	Problem Description	Root Cause	Action Taken	Closure Date	Status
2020-10-27 08:18:07	2020-10-27 12:23:08	0 04:05	515 Pump Cell Station	TE 82534-2 Ripple Test Failure	1. Clog Restrictor	1. UUT observed to have ripple Test failure on marginal specs. 2. Replaced restrictor . 3. Purge out all solvent from tester 4. Ensure tubing to waste 3 is running smoothly 5. Run 2x UUT and Pass 6. Release back to production.	2020-10-27	Close

Test Engineering

Downtime Summary								
Start Date	End Date	Dowtime (Day:Hour :Min)	Tester	Problem Description	Root Cause	Action Taken	Closure Date	Status
2020-09-03 16:00:11	2020-09-30 09:11:35	26 17:1	TE82526-1	Pump Tray tester keeps on restarting Downtime was reactivated as test station start to reset again.	Defective diode at the mounted at relay	1. Replaced power supply p/n: WAT270471 but to no avail 2. Replaced battery CR2032 but to no avail. 3.Unplug and re-plug all cables and connectors but to no avail. 4.Release all pressures from tubing's and air switch and retightened tubing's but to no avail. 5.Replaced PCB p/n:056370 but to no avail. 6.Replaced the air regulator R384-01C but to no avail. 7. Flex to create a video to share to Milford team. 8. HZL raised OESR 204270 to Mark Jussaume - Review in-progress 9.Replaced relay but to no avail. 10.Still fail on Mark Jussaume email 23 Sep 20 to perform troubleshooting.(Checking of relay done. Checking of diode done. Verifying of wiring from relay to power supply connector and CPU J1-b done. All in working condition) 11.Replace plastic tubing and sinker (solvent in). 12.Took out all tubing's and ensure there is no blockage in interface tubing, union or connectors. 13.Purge out solvent from BDSM valve. 14.Replaced fan of tester due to fail to home. 15.Released to production after 3x UUT passed. 16 Station under monitoring 17.Starting to have reset again and recheck relay and diode at the incoming. 18. Borrowed one diode from another Pump tray and behaving good on trial. 19. Release Tester back to the line	2020-09-30	Close

Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – LAR

S/N	LAR / Month	Target	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
1	BAITENG	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
2	KEY POINT	96%	100%	100%	100%	100%	93%	100%	100%	100%	100%	100%	100%	100%
3	JCC/ETLA	96%	100%	100%	100%	100%	100%	100%	100%	NA	NA	100%	100%	85%
4	Technimetal	96%	100%	100%	100%	100%	100%	100%	100%	50%	0%	100%	100%	100%
5	Waters Tech	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%
6	IDEX HEALTH & SCIENCE LLC	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
7	PARKER HANNIFIN	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
8	MRPC	96%	100%	100%	100%	100%	100%	100%	92%	100%	100%	100%	100%	100%
9	FLEXTRONICS SHAH ALAM SDN BHD	96%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
10	CEI	96%	100%	100%	83%	100%	100%	100%	100%	100%	NA	100%	100%	100%

Remarks:

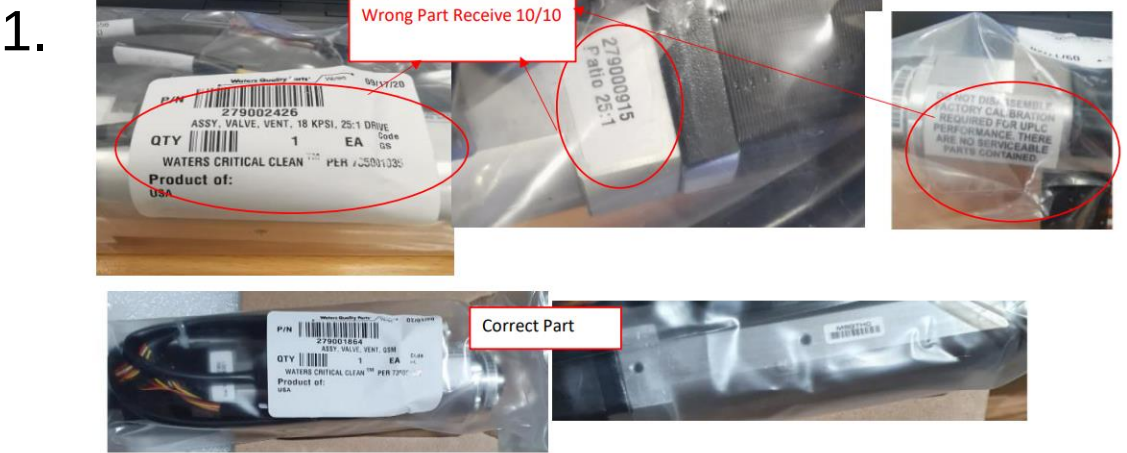
NA: No In-coming lot inspected

Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – LAR

Vendor score below 96% LAR target

No	Supplier	Rejected Lot / Total Lot Received	LAR (%)	Part Number	Part Description	Defect Description	Disposition
1	WATERS TECHNOLOGIES CORP	1/90	99%	WAT-279001864-C	ASSY, VALVE, VENT, QSM	Wrong Part Received	RTV
2	KUNSHAN JIEH CHUENG INDUSTRIAL CO., LTD	2/13	85%	WAT081300-P	ASSY,OPTICS HOUSING	Poor Anodize & missing pin	RTV



Failure Analysis WAT-RW-SKI06331 issued to WATERS TECHNOLOGIES CORP for p/n WAT-279001864-C ,the defect of wrong part received. Correct part p/n is 279001864 but received 279002426.



Failure Analysis WAT-RW-SKI06328 issued to JCC for p/n WAT081300-P, the defect of Poor Anodize & missing pin.

Data Analysis – Quality Issues

Key Suppliers (Top 10) Monthly Overall Quality Performance – dPPM

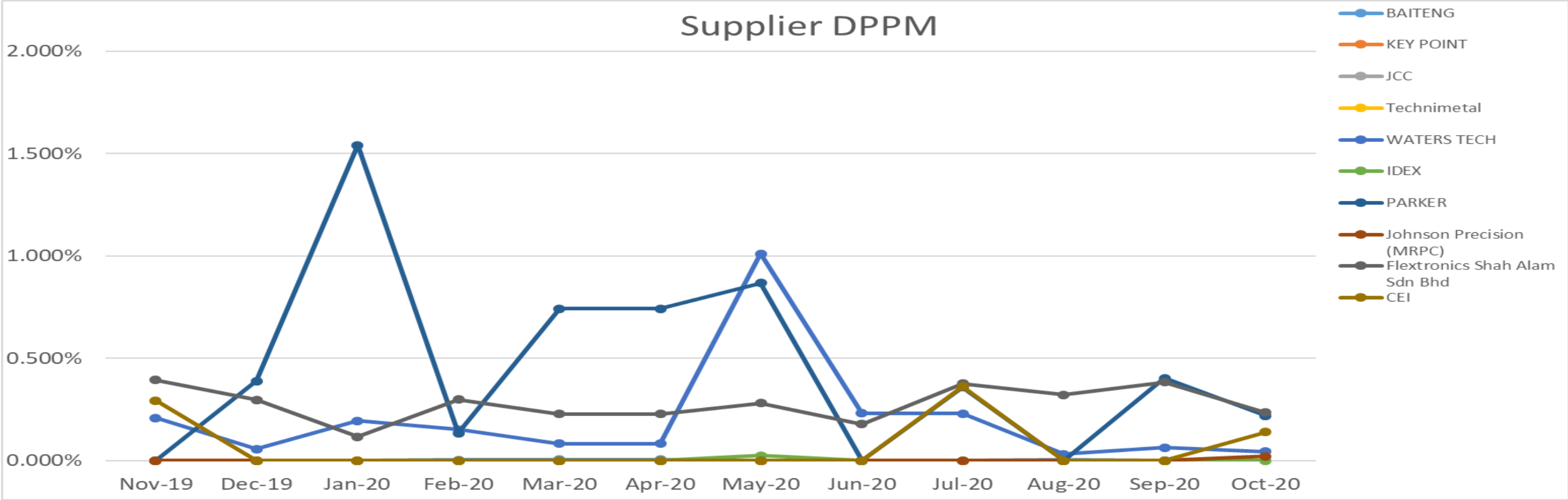
DPPM/Month	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
Supplier	%	%	%	%	%	%	%	%	%	%	%	%
BAITENG	0.000%	0.000%	0.000%	0.004%	0.005%	0.000%	0.000%	0.000%	0.000%	0.005%	0.000%	0.000%
KEY POINT	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
JCC	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	NA	NA	0.000%	0.000%	0.000%
Technimetal	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
WATERS TECH	0.209%	0.057%	0.195%	0.153%	0.083%	0.033%	1.010%	0.232%	0.231%	0.032%	0.064%	0.045%
IDEX	0.000%	0.000%	0.000%	0.000%	0.001%	0.000%	0.025%	0.000%	0.000%	0.000%	0.001%	0.000%
PARKER	0.000%	0.389%	1.541%	0.135%	0.743%	0.197%	0.867%	NA	0.358%	0.000%	0.403%	0.219%
Johnson Precision (MRPC)	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.021%
Flextronics Shah Alam Sdn Bhd	0.394%	0.298%	0.118%	0.299%	0.229%	0.443%	0.282%	0.179%	0.376%	0.322%	0.383%	0.235%
CEI	0.294%	0.000%	0.000%	0.000%	0.000%	0.120%	0.000%	0.000%	0.362%	0.000%	0.000%	0.141%

Remarks:

NA – No receipt of delivery

Data Analysis – Quality Issues

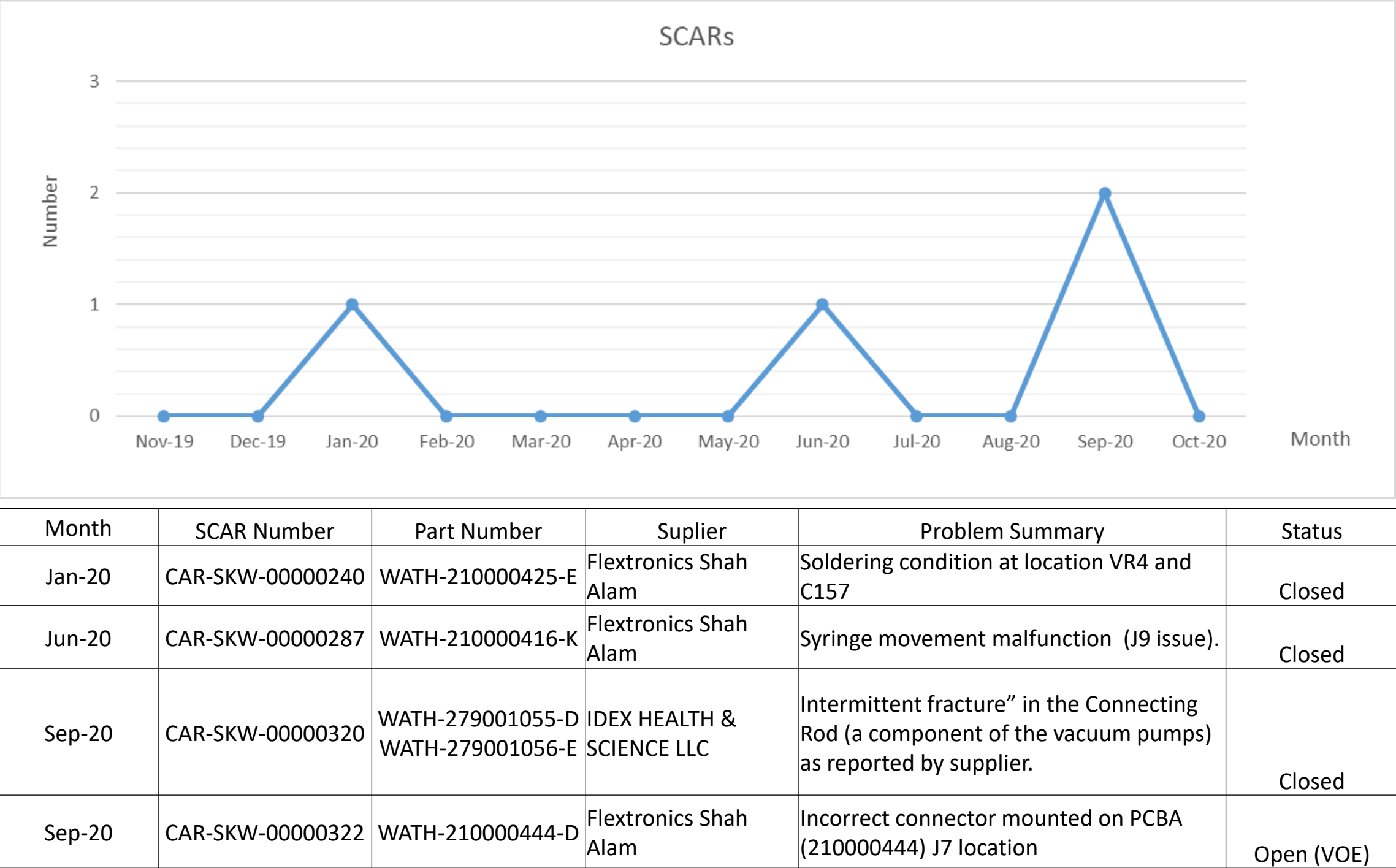
Key Suppliers (Top 10) Monthly Overall Quality Performance – dPPM



Month	FA Number	Part Number	Suplier	Problem Summary	Status
Jan-20	WAT-RW-SKI05817	WATH-279001810-L	PARKER HANNIFIN	Failed test Input A/B/C/D Prime with MeOH	Closed
Sep-20	WAT-RW-SKI06304	WATH-210000345-M	FLEXTRONICS SHAH ALAM SDN BHD	1) Test loader download failed (Fatal Error & serial port error). 2) Test reboot firmware failed (Fatal Error – Assertion Failed). 3) Test leak detect connected failed.	Open
Sep-20	WAT-RW-SKI06305	WATH-210000425-E	FLEXTRONICS SHAH ALAM SDN BHD	Plunger Homing Fault(0) during Rear Panel Test	Open
Oct-20	WAT-RW-SKI06330	WAT-WAT270782-01	MRPC Northeast Division	Unable to screw in fully	Open

Data Analysis – Quality Issues

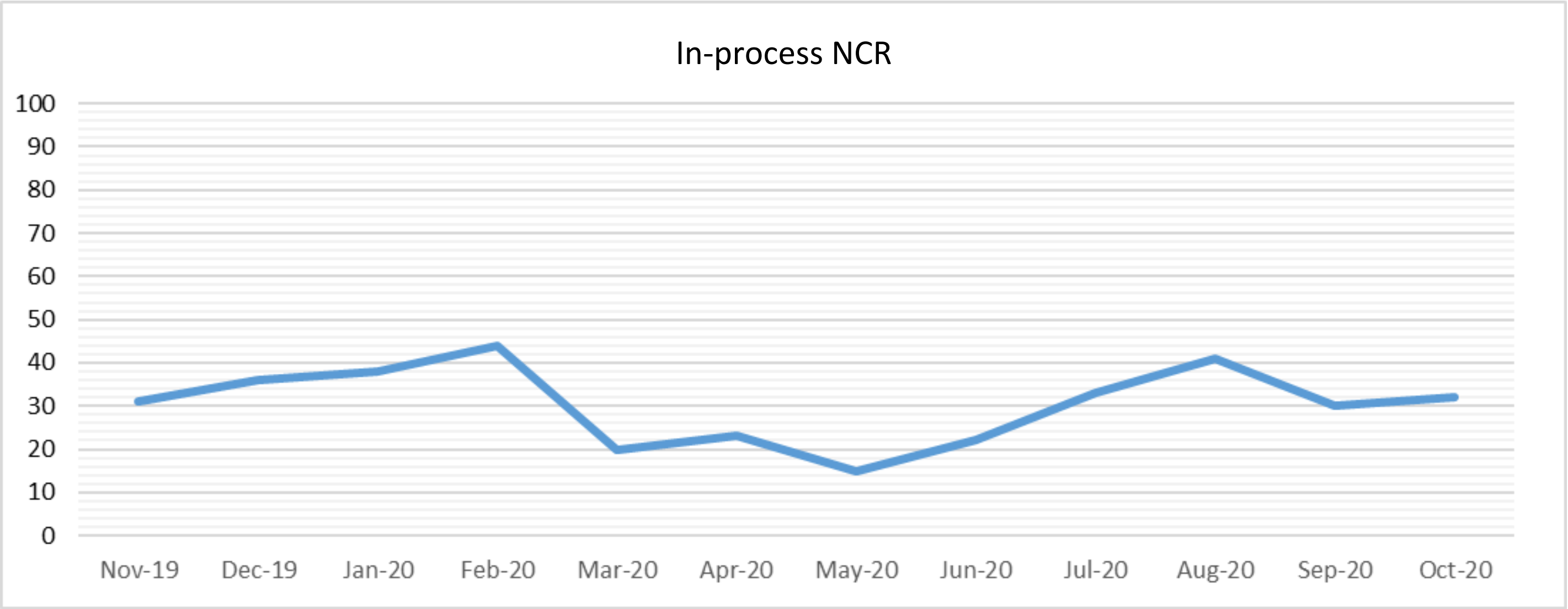
Key Suppliers (Top 10) Monthly Overall Quality Performance – SCARS



Data Analysis – Quality Issues

Quality Issues (Process - Material) – NCR (running 12 months)

Month	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
NCR	31	36	38	44	20	23	15	22	33	41	30	32



Data Analysis – Quality Issues

Quality Issues (Process - Material) – Repeated NCR / NCR Update

No	Supplier	Part No.	Part Description	Non-conformance	Defect Category	Non-Conformance Repeated		Rejected Qty	Parts usage	Percentage	Out of Control Limit	Action Taken/Status	Remark
1	WATERS TECHNOLOGIES CORP.	WAT-289001940-P	ASSY, CHECK VALVE, DOUBLE BALL	Failed Dynamic Leak Test	Test Failure	Oct'20	Sep'20	1	279	0.358%	No	Under P-chart monitoring	Sep'20: 1 pc
2	FLEXTRONICS SHAH ALAM SDN BHD	WATH-210000425-E	ASSY, PCB PUMP DRIVER	Unable to activate GPV during Solvent Inlet Plumbing Verification	Test Failure	Oct'20	Sep'20	1	386	0.259%	No	Existing Failure Analysis Form WAT-RW-SK106305, status: Open	Sep'20: 2 pcs

Data Analysis – Quality Issues

Audit Schedules

Supplier Audit Schedule 2020											
JUL		AUG		SEP		OCT		NOV		DEC	
Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
+CMTI	+CMTI			+JCC	+JCC	+Baiteng	+Baiteng	+Fuyu	+Fuyu		
Supplier Audit Schedule 2021											
JAN		FEB		MAR		APR		MAY		JUN	
Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual	Planned	Actual
+Flextronics Shah Alam +Trend						+Foamtec				+Key Point	

Remarks:

* – Common supplier

+ - Process Audit

Data Analysis – Quality Issues

Audit Results, Findings and Closures

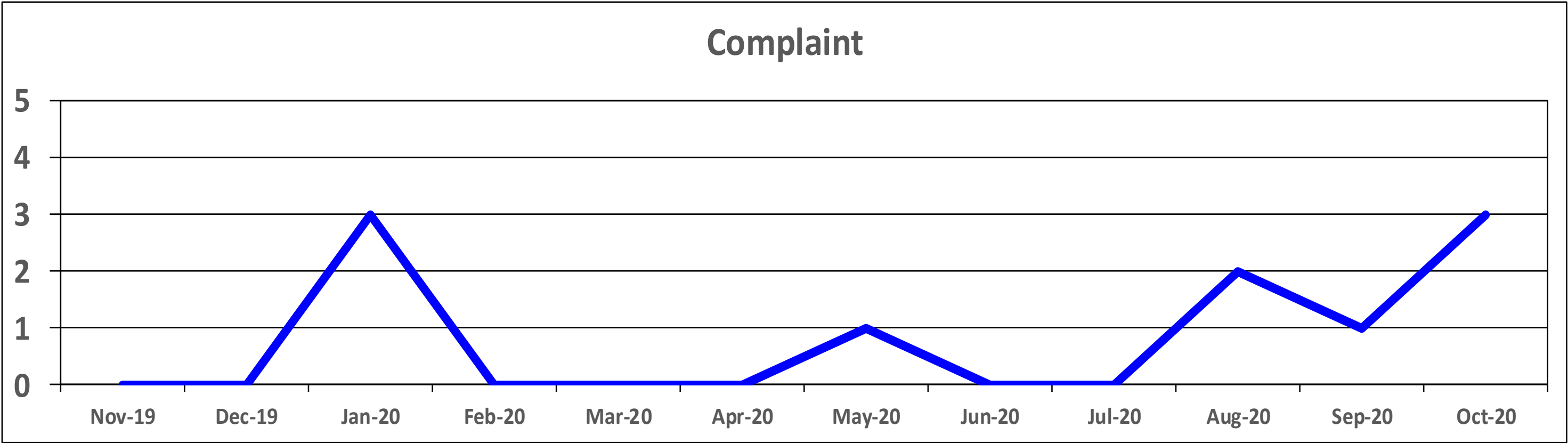
FU YU CORPORATION LIMITED					
Category	Findings	Open	Close	Target to Close by	Status Update
NC	TBA	TBA	TBA	TBA	Open

Notes:
On-site Process Audit on 19-Nov-20

Customer & Field Complaints

Customer & Field Complaints Trending

Month	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
Complaint	0	0	3	0	0	0	1	0	0	2	1	3
Open	0	0	0	0	0	0	0	0	0	2	1	3
Closed	0	0	3	0	0	0	1	0	0	0	0	0



Customer & Field Complaints

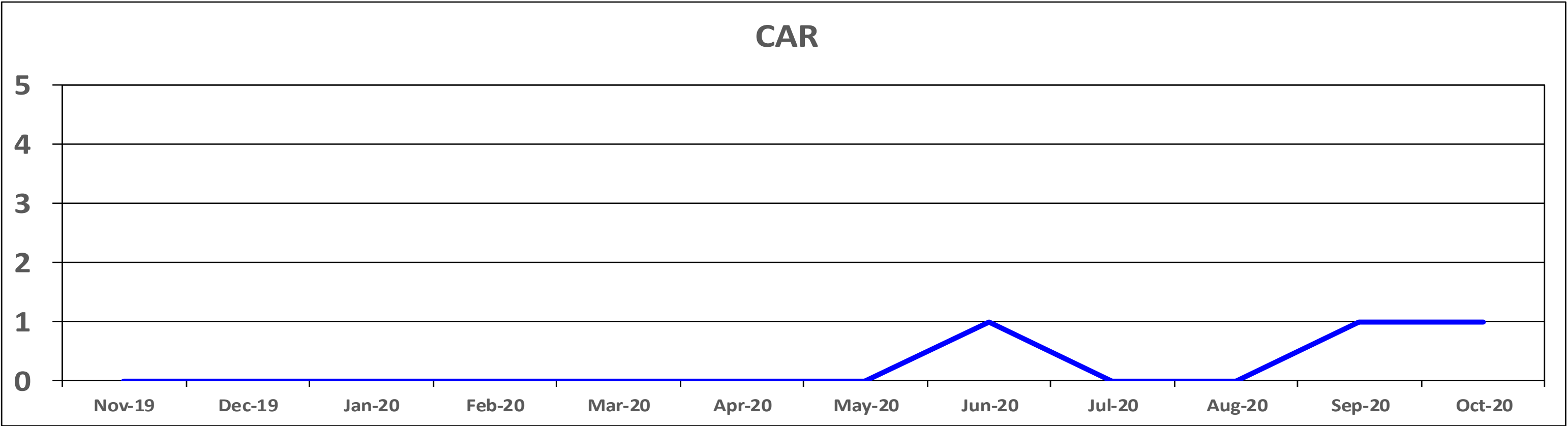
 Closed

 Open

Product Family	Nov' 19	Dec' 19	Jan' 20	Feb' 20	Mar' 20	Apr' 20	May' 20	Jun' 20	Jul' 20	Aug' 20	Sep' 20	Oct' 20	Total	Remarks
Alliance	-	-	3	-	-	-	1	-	-	-	-	2	6	<u>Jan'20</u> - one PCBA 210000425 found with bad soldering on VR4 and C157 (Alliance SN:F19SM7500A, 210000425 SN:140519120M) – Closed <u>Jan'20</u> - Alliance SN M18SM4184A was found to have needle malfunction error. The FSE found red/white wire had come out of the motor 279000928 Molex connector. – Closed <u>Jan'20</u> - Alliance unit SN K19SM4617A was found to have missing outlet ferrule fitting at customer lab in China. – Closed <u>May'20</u> – Alliance Syringe Drive Movement Error upon Startup - Closed <u>Oct'20</u> - Alliance Top Cover Screw Stuck - Open <u>Oct'20</u> - Alliance Pump Tray Screw is stuck - Open
Detector	-	-	-	-	-	-	-	-	-	1	-	-	1	<u>Aug'20</u> - an increase in start-up/early life failures of PDA detectors which appear to be related to charge amp PCB (PN 210001203 and 210001164) The failure mode observed is “Dark Current Too Low” in the majority of cases. - Open
Solvent Manager	-	-	-	-	-	-	-	-	-	-	-	-	0	NA
PUMP	-	-	-	-	-	-	-	-	-	-	-	1	1	<u>Oct'20</u> - 515 Pump (WAT207000) leaking issue found in Waters Milford. – Open
Spares	-	-	-	-	-	-	-	-	-	1	1	-	2	<u>Aug'20</u> - feedback from Waters FSE in UK that PN 700011783 seal pack rebuild kit found 1unit with missing seal. - Closed <u>Sep'20</u> - HC spares with 210000444 PCB mounted wrong connector - Open

CAR Trending

Month	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
CAR	0	0	0	0	0	0	0	1	0	0	1	1
Open	0	0	0	0	0	0	0	0	0	0	1	1
Closed	0	0	0	0	0	0	0	1	0	0	0	0

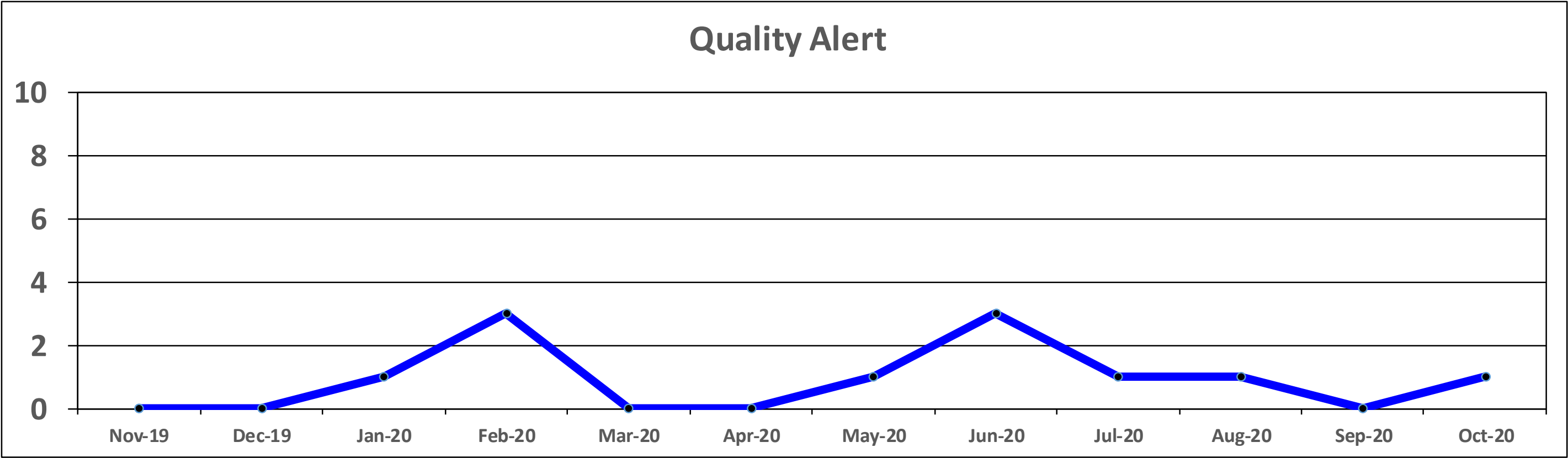


Product Family	Nov '19	Dec '19	Jan '20	Feb '20	Mar '20	Apr '20	May '20	Jun '20	Jul '20	Aug '20	Sep '20	Oct '20	Total	Remarks
Alliance	-	-	-	-	-	-	-	1	-	-	-	-	1	SCAR-SG200601: Jun'20 – Alliance Syringe Drive Movement Error upon Startup. - Closed
Detector	-	-	-	-	-	-	-	-	-	-	-	-	0	NA
Solvent Manager	-	-	-	-	-	-	-	-	-	-	-	-	0	NA
PUMP	-	-	-	-	-	-	-	-	-	-	-	1	1	SCAR-SG201001: Oct'20 - Operator was observed not following ASP WAT207006 Rev 06, step 4.0 - Open
Spares	-	-	-	-	-	-	-	-	-	-	1	-	1	SCAR-SG200914: Sep'20 - HC spares with 210000444 PCB mounted wrong connector - Open

In Process - Quality Alert

Quality Alert

Month	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20
Quality Alert	0	0	1	3	0	0	1	3	1	1	0	1
Open	0	0	0	0	0	0	0	0	0	0	0	0
Closed	0	0	1	3	0	0	1	3	1	1	0	1



QMS Update

NA

AOB

NA

