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Process Improvement with the use of Beckman Coulter Access 2 Immunoassay System

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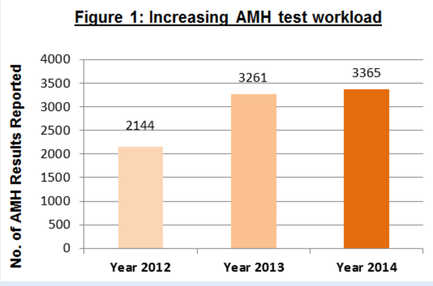
BACKGROUND

Anti-Müllerian hormone (AMH) is a hormone produced by reproductive tissues. Its role and the amount normally present varies depending upon sex and age. AMH testing is useful in women who are undergoing assisted reproduction procedures and as well in predicting onset of menopause. AMH testing in infants is useful in determining the sex of baby (ambiguous genitalia). Before project implementation, AMH testing in KKH is done by Beckman Coulter Gen II ELISA reagent kit on Biorad Evolis analyser.

PROBLEM

1) Batch testing: To accumulate for 39 patient specimens in a batch so as to maximize the usage of the whole ELISA reagent kit.
2) Validity of AMH batch testing is determined by QC results at the end of the run.
3) Positive bias performance in external quality assurance (EQA) program.
4) Long analytical time: about 5 hours per batch
5) Long turn-around time (TAT): about 4 days
6) Increasing workload since Year 2012 (Figure 1)

Figure 1: Increasing AMH test workload



AIM

To enhance efficiency of AMH testing. The SMART principles was used to define the project scope and set targets (Table 1).

S	**Specific**	To enhance efficiency in AMH testing.
M	**Measurable**	1) To reduce analytical time in AMH testing by 50%. 2) To reduce number of serum aliquoting for AMH batch testing by 40%. 3) To reduce batch testing interval by 20%. 4) To reduce turn-around time (TAT) of AMH reporting by 50%.
A	**Attainable**	Change of AMH testing method
R	**Relevant**	**Align with KKH's strategic objectives (Year 2015):** ❖ Patient-Centred Processes & Services (Improve TAT of AMH result report) ❖ Clinical Outcome & Patient Experience (Improve patient satisfaction) ❖ Financial (Achieve cost saving)
T	**Time-bound**	To start project in Jan 2015 and complete it within a year.

Table 1: Target setting by using SMART

METHODOLOGY

Fishbone diagram (Figure 2) is used to identify the possible root causes for inefficiency of AMH testing and the pareto chart (Figure 3) is used to identify the major root cause - accumulate for 39 patient AMH tests in a batch. With the use of brainstorming and weighted decision matrices (Figure 4 & Tables 2 to 5), the team then decided to use Beckman Coulter Access 2 Immunoassay System (Figure 5) in this project.

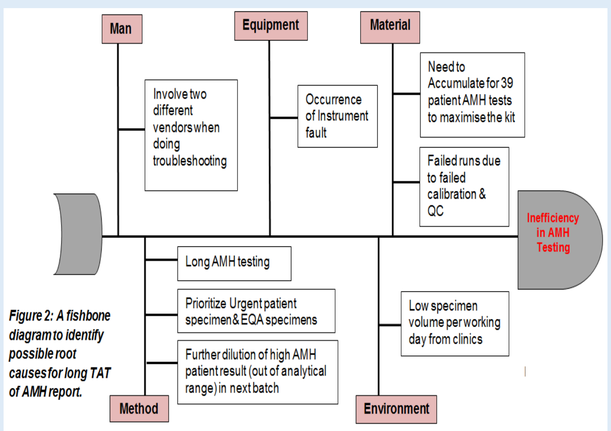


Figure 2: A fishbone diagram to identify possible root causes for long TAT of AMH report.

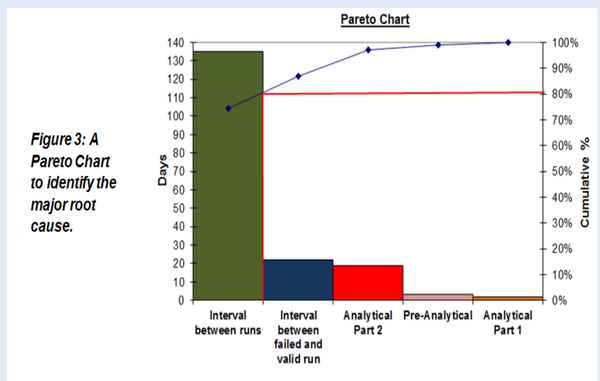


Figure 3: A Pareto Chart to identify the major root cause.

Days taken in Year 2014	135	22	19	3	2
Cumulative %	75	87	97	99	100

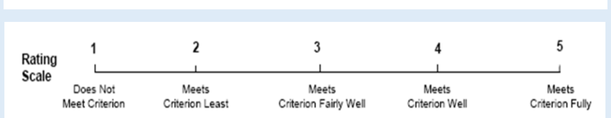


Figure 4: A rating scale is used to rate the evaluation criteria.

Evaluation Criterion	Description	Weightage (W)
Availability of Product	The product is readily available in the market.	0.3
Cost-Effectiveness	The solution is able to provide long term consistent benefit.	0.3
Reliability of Test Result	The product is validated for patient testing.	0.4

Table 2: Evaluation Criterion and its Weightage for Solution Selection

Possible Solutions	Criteria Score (Total Member Rating Score x Weightage)			Total Score	Rank
	Availability of Product	Cost–Effective	Reliability of Test Result		
Perform manual AMH testing with the use of same Beckman Coulter Gen II ELISA reagent kit.	15.9	4.5	19.2	39.6	2nd
Request for Beckman Coulter Anti-AMH Gen II Antibody Coated Microtitration strips for manual method testing.	3.6	8.1	16.0	27.7	3rd
Change to different new analyser to perform AMH testing.	18	13.2	18	49.2	1st
Source for other AMH ELISA reagent to use on Biorad Evolis analyser.	3.6	3.6	6.0	13.2	4th
Explore current analysers in DPLM to do AMH testing.	3.6	3.6	4.8	12.0	5th

Table 3: Selection of Solution using Weighted Decision Matrix

Evaluation Criterion	Description	Weightage (W)
A. Performance of EQA Program	The analyser/method has good peer performance in EQA program.	0.2
B. Availability of Neonatal Reference Interval for AMH	Neonatal reference interval for AMH is validated on the analyser.	0.2
C. Cost-Effectiveness	The solution is able to provide long term consistent benefit.	0.3
D. Ease of operation	The analyser is easy to use for testing.	0.1
E. Random Access	Random access to testing in analyser is available.	0.2

Table 4: Evaluation Criterion and its Weightage for Vendor Selection

Possible Vendor	Criteria Score (Total Member Rating Score x Weightage)					Total Score	Rank
	A	B	C	D	E		
Beckman Coulter-Access 2 Immunoassay System	9.6	11.4	16.5	4.8	11	53.3	1st
Roche Diagnostics-Cobas 4000 (e411)	8.6	2.4	7.2	4.8	11	34	2nd

Table 5: Selection of Vendor using Weighted Decision Matrix

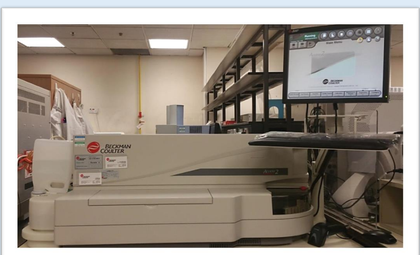


Figure 5 : Beckman Coulter Access 2 Immunoassay System

RESULTS

1) 55% Reduction in Time Taken in Analytical Phase of AMH testing (Table 6):

	Beckman Coulter AMH Gen II on Biorad Evolis		Beckman Coulter Access 2 Immunoassay System	
	Process	**Time Taken (mins)**	**Process**	**Time Taken (mins)**
Analytical Part 1	Step 1) Thaw patient aliquots, calibrators & QCs	30	Step 1) Thaw patient aliquots& QCs	30
	Step 2) Daily Maintenance of Biorad Evolis	(15)	Step 2) Top up Bulk Supplies (Empty waste, Wash buffer, reagent, Reaction Vessels & Waste bag)	(5)
	Step 3) Topping up of bulk supplies (Reconstitute wash buffer, top up pipette tip and loading of microtitre plate).Mixing of reagents on the rotator & loading of reagent into Biorad Evolis	(15)	Step 3) Daily Maintenance of Access 2	(15)
	Step 4) Centrifuge patient aliquots	6	Step 4) Running QC	40
	Step 5) Pipetting and loading of calibrators & QCs	(4)	Step 5) Centrifuge patient aliquots & then place aliquots in racks	(10)
	Step 6) Loading of patient aliquots and Anti-AMH Gen II Antibody Coated Microtitration strips	(2)	Step 6) Check QC & load patient aliquots to run	2
Analytical Part 2	Step 1) AMH testing in Biorad Evolis	300. Assuming 39 patients in a batch.	Step 1) AMH testing in Access 2	40 per test. Will take 78 mins if assuming 39 tests in a batch
	Total	***336 (5hr 36mins)***	***Total***	***150 (2hr 30mins)***
	% of Analytical Time Reduced: 55%			

Table 6: Time Taken in Analytical Phase Before and After Project Implementation
(The minutes in brackets refer to the process can be done during the waiting time of another process.)

2) 23% Reduction in Batch Testing Interval (Figure 6):

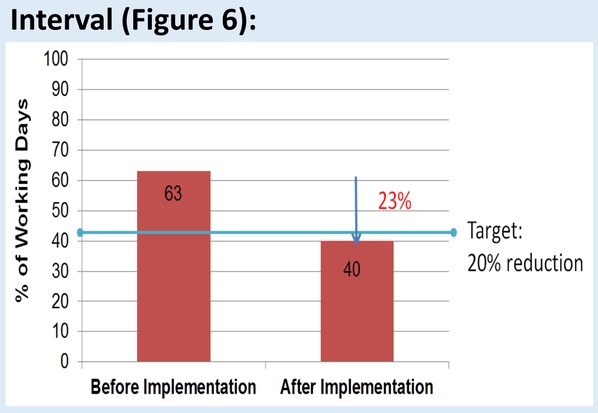


Figure 6 : Batch Testing Interval days

3) 41 % Reduction in Consumables for Aliquoting Patient Serum (Figure 7):

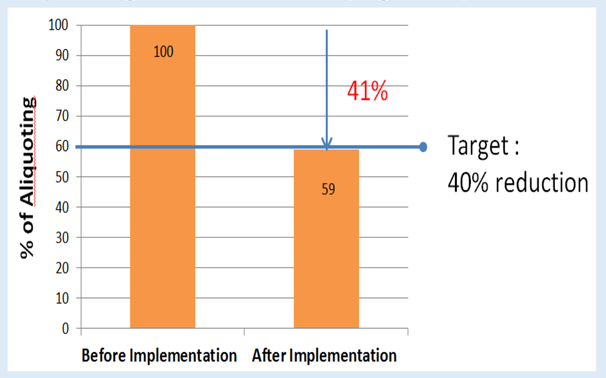


Figure 7 : Reduction in Aliquoting

4) Faster TAT in AMH Result Reporting (Figure 8):

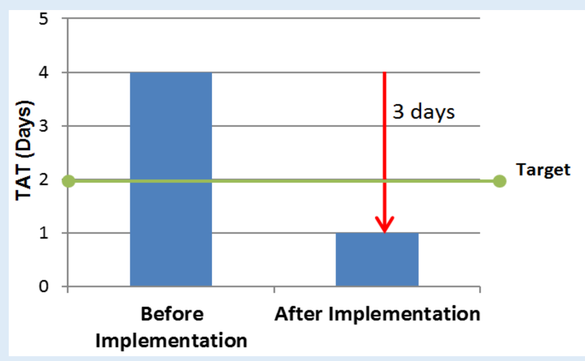


Figure 8 : TAT in AMH Result Reporting

5) Cost saving of S$162774 (3-year period) after migration from direct purchase to Cost Per Reportable scheme (Table 7):

	Beckman Coulter AMH Gen II ELISA Reagents on Biorad Evolis (3327 patients in Year 2014)	Beckman Coulter Access 2 Immunoassay System (Assuming 3327 patients in Year 2016)
Estimated Total Amount Spent in 1 Year (Failed runs, Valid QC and Calibration, Manpower, Consumables, Service Contract Agreement, patient tests and EQAs)	S$94659	S$40401
Estimated 3-Year Cost Saving after Project Implementation	S$162774	

Table 7 : Cost saving before and after Project implementation

6) Intangible Benefits:

a) Enhance Patient Services and Increase Patient Satisfaction – AMH result can be reported within a shorter time and doctors can provide earlier treatment to the patient.

b) Increase Confidence Level of AMH Result Reporting – No longer facing with positive bias performance and comparable with the same peer group.

CONCLUSION

We have successfully implemented Beckman Coulter Access 2 Immunoassay System for AMH testing in Nov 2015. With this new analyser, AMH testing efficiency is enhanced. In order to make use of the current setting of Beckman Coulter Access 2 Immunoassay System, the laboratory will be evaluating Vitamin D assay in July 2016 and also planning to evaluate Inhibin B assay in the near future. In addition, KKH is the first hospital in Singapore to use Beckman Coulter Access 2 Immunoassay System to do AMH assay testing. We can be a role model for others to follow.