GERMANO DE SOUSA LABORATORY MEDICAL CENTER

A journey of Quality: Innovation, quality and accuracy

> Rita Ribeiro Lisbon, Portugal

LESSONS LEARNED FROM OUR LAB'S EIGHT-YEAR USE OF QUALITY MANAGEMENT METHODS TO CHANGE THE CULTURE, BOOST PRODUCTIVITY, INCREASE QUALITY

- 40 Years of History: Our Lab's Lean journey
- Clinical Practice Improvement Landmaks:

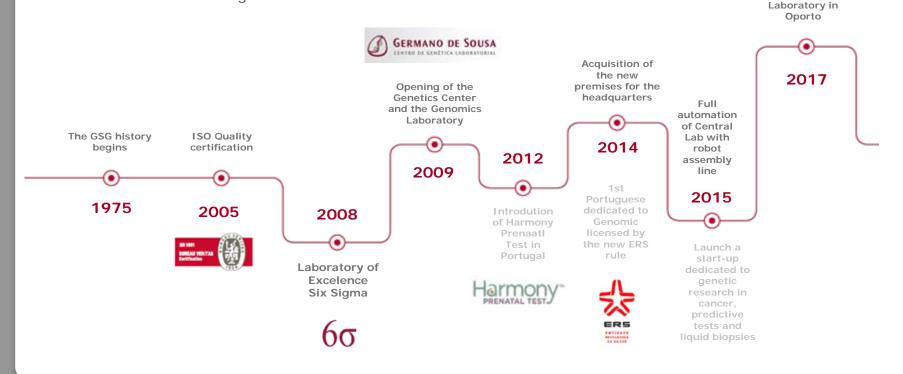
ISO9001, Lean Six Sigma Philosophy, Redesign

- Three successful process improvement projects
- Lessons learned
- Next steps: now is the future

THE CHANGE BEGINS WHEN SOMEONE SEES THE NEXT STEP

LANDMARKS IN OUR HISTORY

The Germano de Sousa Group (GSG) has been firmly established in clinical laboratories for more than 40 years. The Group grew and developed in the heart of the scientific community and our strength lies in the ability to combine science with management and innovation skills.





Opening of

Central

40 YEARS OF HISTORY

CENTRES OF EXCELLENCE

- > Prenatal Diagnosis
- > Combined First-trimester Screening
- > Combined Second-trimester Screening
- > Harmony Prenatal Test
- > Precision Medicine
- > Oncogenomics, Pharmacogenomics
- > Genetic Markers of Hereditary Neoplasms
- > Oncological Diagnosis (Tumour Markers, HPV, PCa3)
- > Dyslipidaemia Studies
- > Lipid parameters and lipoproteins
- > Identification and determination of LDL and HDL subfractions
- in patients at risk
- > Study of Systemic Autoimmune Diseases
- (Systemic Lupus Erythematosus, Rheumatoid Arthritis, Scleroderma, etc.)

- > Study of Organ-Specific Autoimmune Diseases (Thyroiditis, Hepatic, Intestinal, etc.)
- > Study of Neurological Autoimmune Diseases
- > Immuno-allergology (RAST / ISAC)
- > Morphological examination of peripheral blood and bone marrow
- > Flow cytometry
- Genetic studies
- > Autoimmune Diseases
- > Haemato-oncology



40 YEARS OF HISTORY

GERMANO DE SOUSA IN NUMBERS

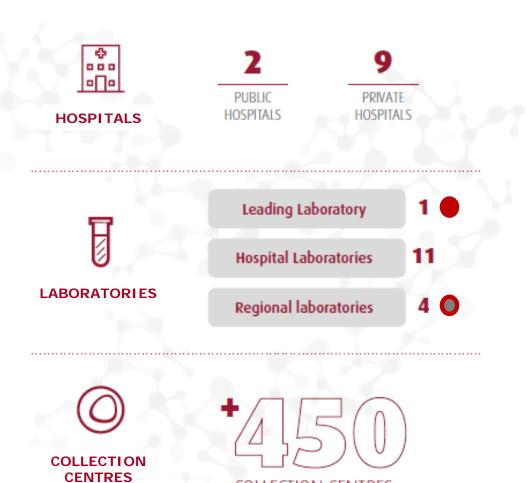
The skills of our human resources, strong investment in technological capacity and research and innovation policies coupled with specialised management make Germano de Sousa the largest private operator in Portugal.







GEOGRAPHICAL PRESENCE



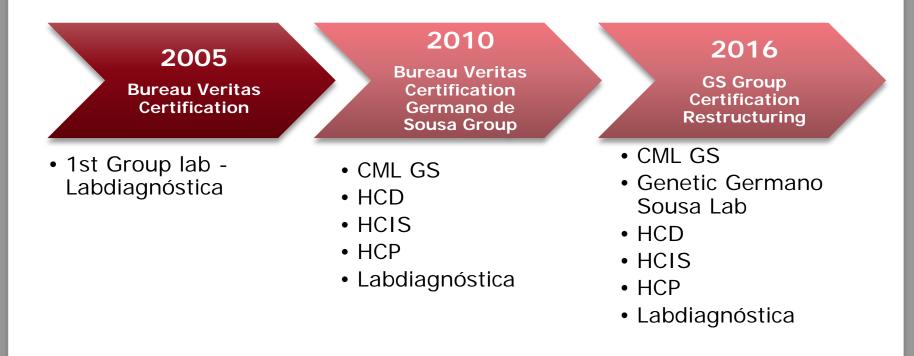
COLLECTION CENTRES



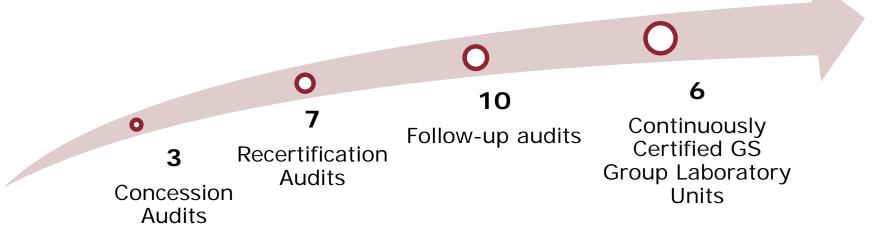
40 YEARS OF HISTORY

THE GERMANO DE SOUSA GROUP HAS A QUALITY MANAGEMENT SYSTEM [ISO 9001]

The application of these principles as a strategy of continuous improvement and control of their performance, meeting the requirements, needs and expectations of users, in an effective and efficient.



SUSTAINING THE USE OF THE ISO 9001 QUALITY MANAGEMENT SYSTEM



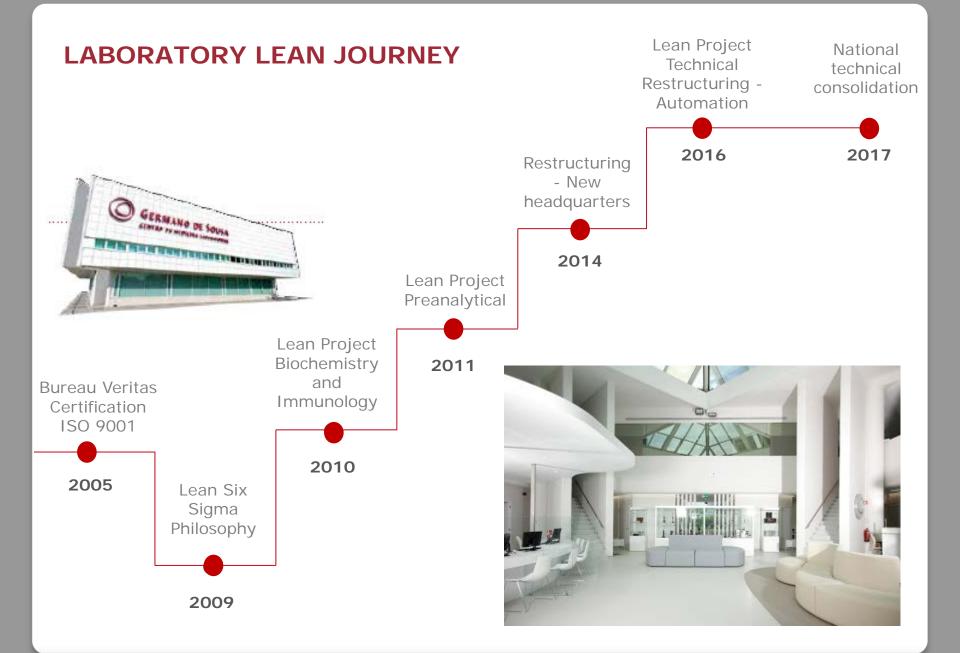












CLINICAL PRACTICE IMPROVEMENT APPROACH

Customer Focus

- Satisfaction of the expectations and demands of the Clients,
- Involvement of the Administration, Employees, Suppliers, Doctors and Entities.

Resource management

- Scientific method applied to our work
- Training and follow-up of all Employees
- Competent and conscious execution of own responsibilities
- Identify waste: reduce or eliminate it

Employee responsibility and involvement

• All Employees responsibility Leaders Communicating and understanding the team

Compliance with standards and good laboratory practices



LEAN TOOLS

- 5 Why's
- Rapid Process Improvement Workshops
- Visual management
- Inventory management
- Metrics

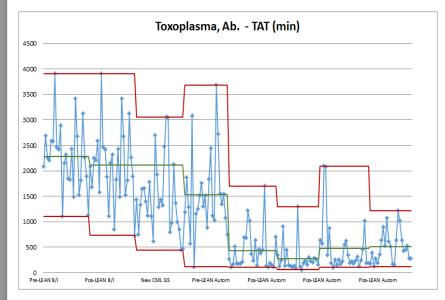


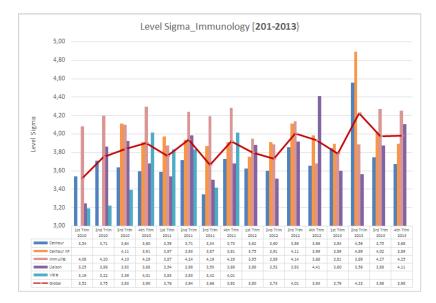
DMAIC PROJECT

- Orientation of the company's objectives in a continuous improvement associated with the reduction of costs related to non-quality.
- In this project we want to find a solution that allows us to improve not only technical performance but customer satisfaction.

Focus on Reduction TAT: Eliminate the repetitions performed per equipment, according to the characteristics of the method used and studies of reproducibility and capacity.

DMAIC PROJECT





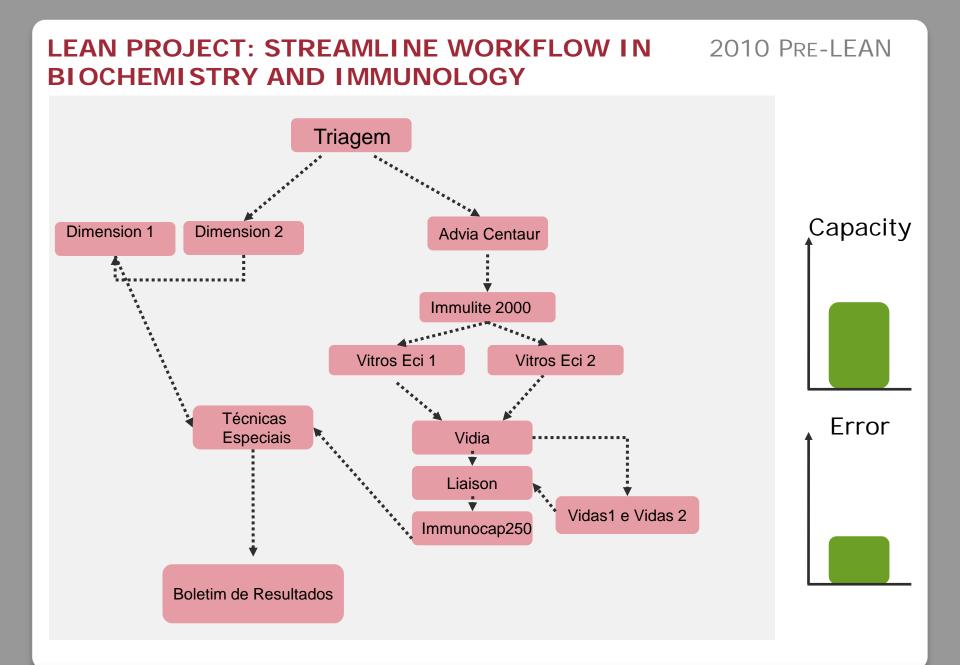
PROBLEM POTENTIAL SOLUTION Implementation of algorithm for Repetitions due to automatic programming of dilutions of dilution biological samples Increase cooling in the field of realization of Biochemistry - Dimension Influence of temperature on some parameters Intensive training to new technician, and recycling to be provided to all technician, with review of pre-analytical procedures Equipment: precision Correlation studies were performed for the anaysed parameters Vidia equipment with other equipment on the market.

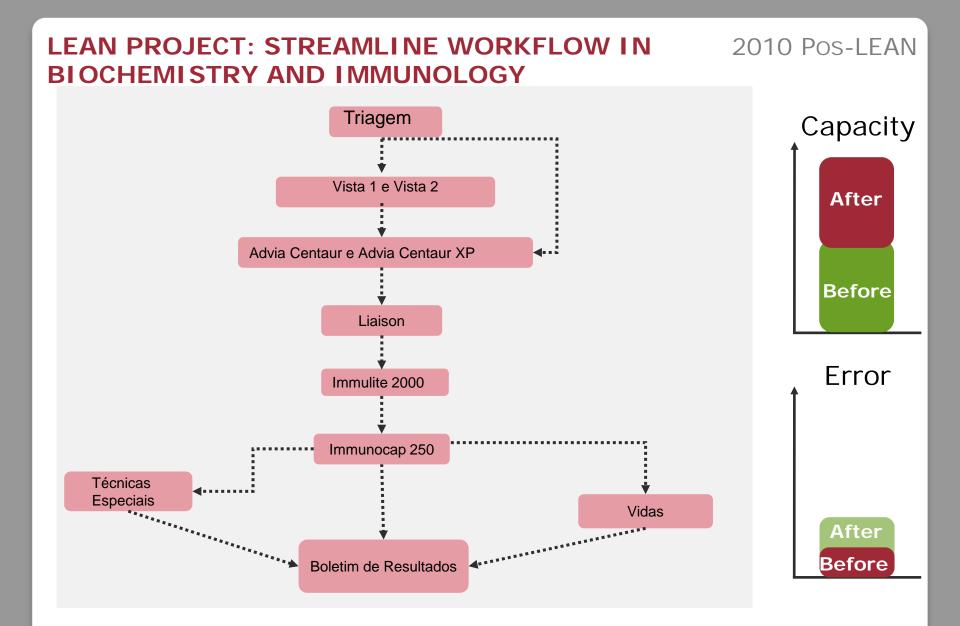
TAT improvment36% reduction time

 Repetitions performed per equipment:
 Sigma 3.50 to 4.00

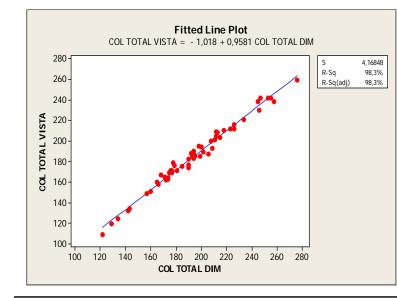
LABORATORY JOURNEY - CREATING THE FUTURE

2009 DMAIC





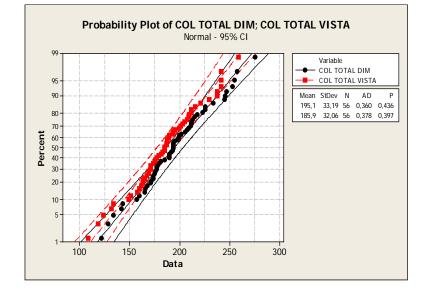
CHANGE MANAGEMENT - STRATEGIC AND OPERATIONAL LEVELS



Correlations: COL TOTAL DIM; COL TOTAL VISTA

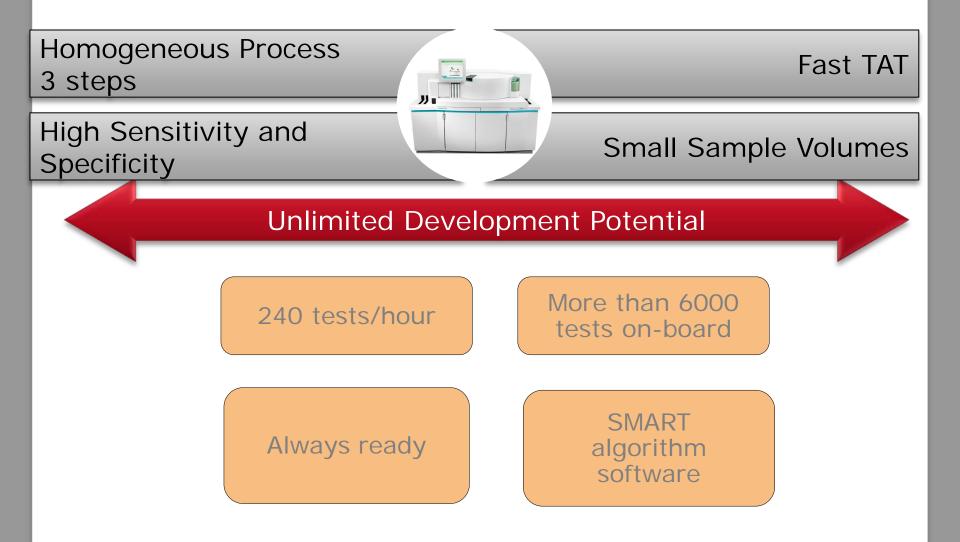
Pearson correlation of COL TOTAL DIM and COL TOTAL VISTA = 0,992 P-Value = 0,000

LEAN redesigns, new equipment acquisition and change methodologies, carried after validation of methods. SUSTAINABLE IMPROVEMENT

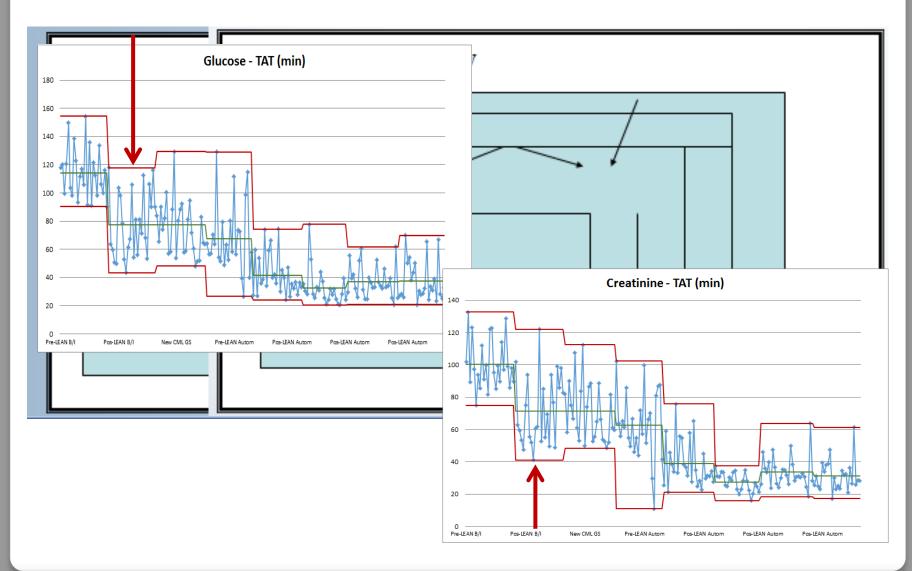


	COL TOTAL DIM	COL TOTAL VISTA
MÉDIA	195,05	185,86
SD	6,50	
CV%	3,41	
MEDIANA	194,00	185,00
SD	6,36	
CV%	3,36	
VAR %	-4,64	
VAR u	-8,79	
CVw [betw een- subject bioloical variation]	15,2	

TECHNICAL CONSOLIDATION - VISTA 1500: WHAT WE WANTED TO ACHIEVE



TECHNICAL CONSOLIDATION - VISTA 1500 LEAN PROJECT BIOCHEMISTRY AND IMMUNOLOGY



LEAN PROJECT BIOCHEMISTRY AND IMMUNOLOGY

2010 Pre-LEAN







LEAN PROJECT BIOCHEMISTRY AND IMMUNOLOGY

2010 Pos-LEAN





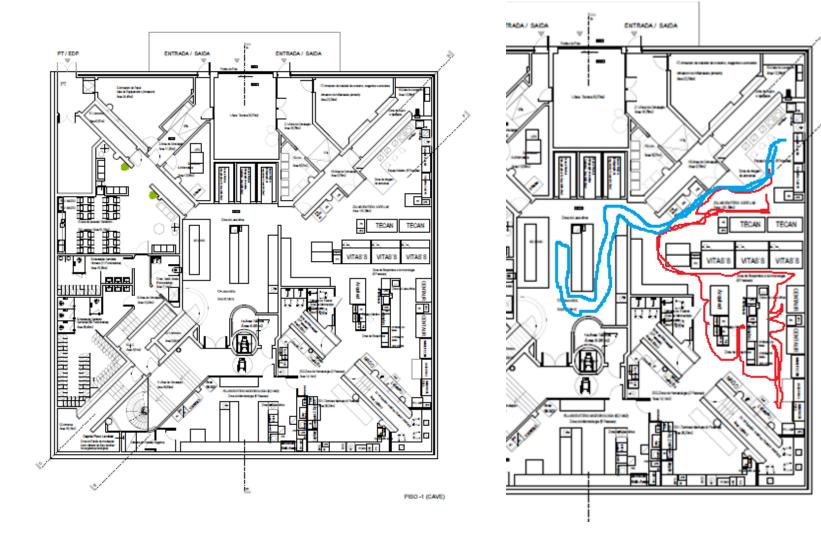




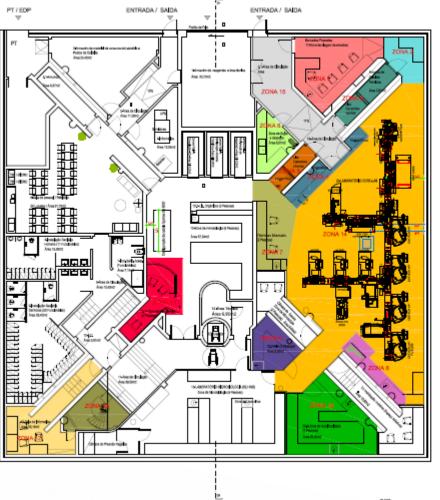








2015 PRE-LEAN



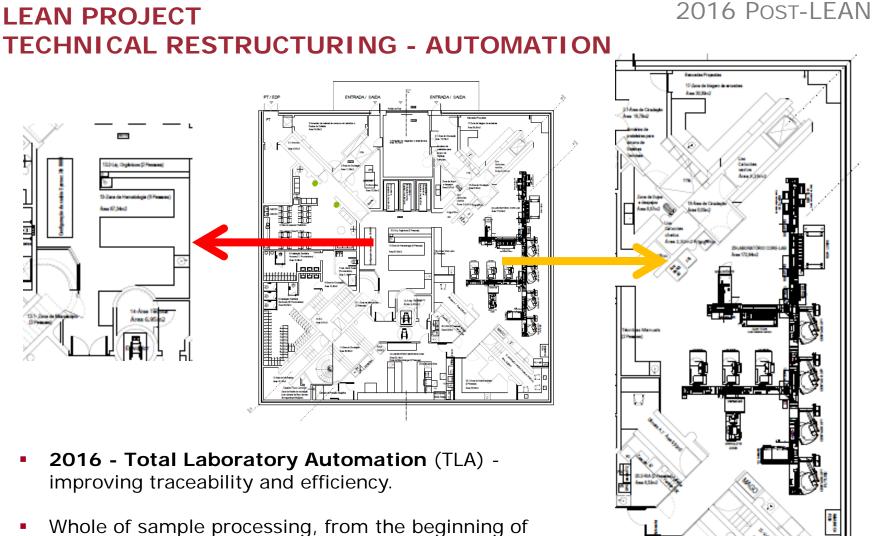
Zonas de Intervenção

Zona 1 - zona de trlagem de amostras Zona 2 - zona de triagem/circulação Zona 3 - arrumos de geleiras térmicas e lixo, calxotes vazlos Zona 4 - frigorificos, 1 posto de trabalho Zona 5 - frigorifico e lixo, calxotes chelos Zona 6 - zona de sujos e despejos Zona 7 - técnicas manuals Zona 8 - bancada e Immunocap 250 Zona 9 - RIA Zona 10 - zona de autoimunidade Zona 11 - zona de microscópio Zona 12 - sala de Informática Zona 13 - zona técnica / esgotos Zona 14 - CORE-LAB Zona 15 - área de circulação

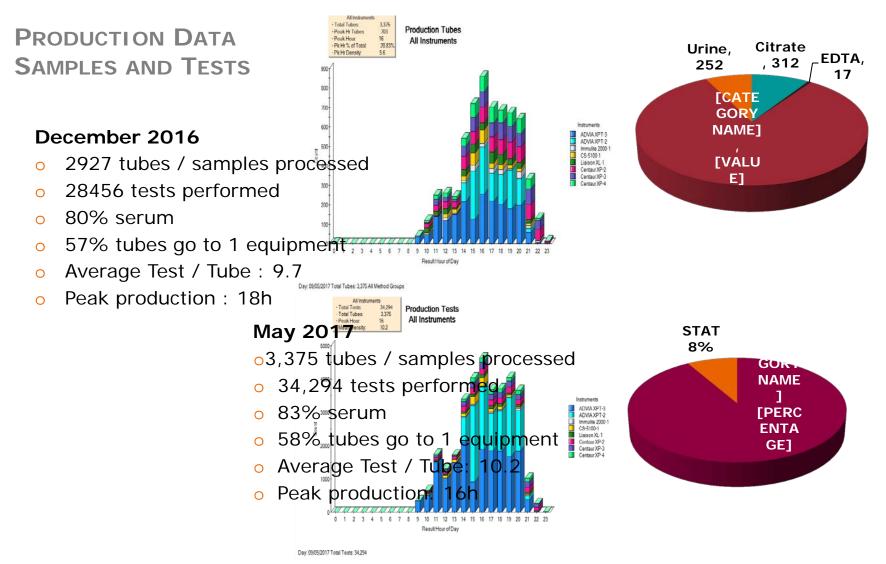
CODE GRAPHING

2016 Post-LEAN

PISO -1 (CAVE)

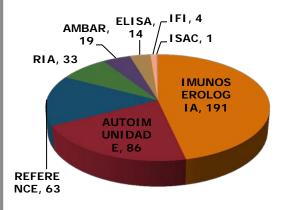


Whole of sample processing, from the beginning of the workflow inside the lab (check-in) to the end (disposing), including any step in pre-analytical, analytical and post-analytical phases.



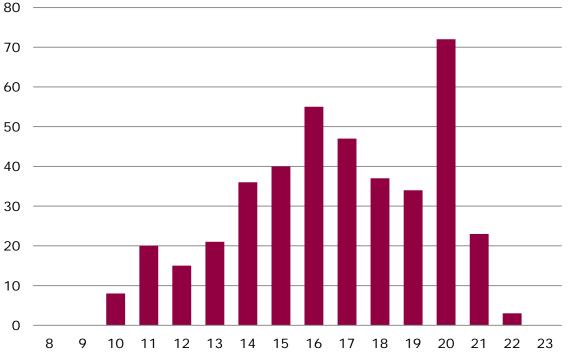
PRODUCTION DATA ALIQUOTS



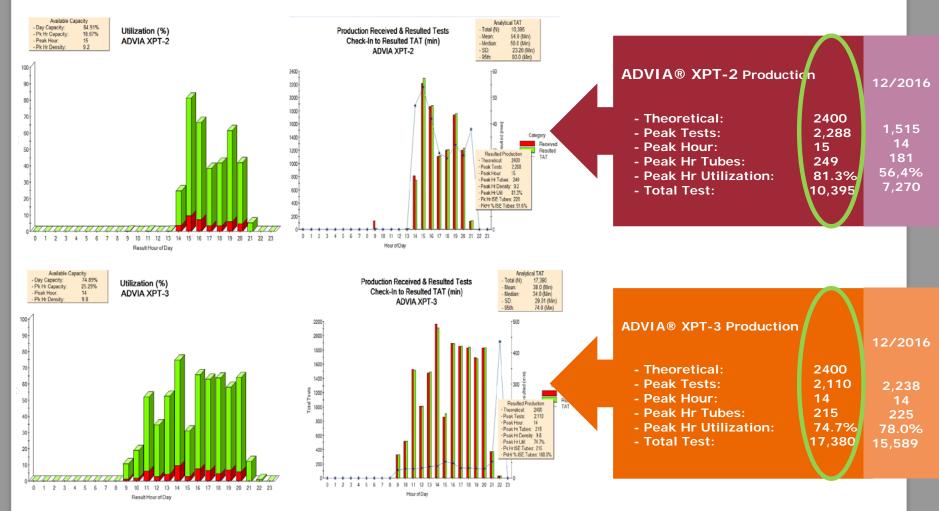


May 2017 411 Aliquots 47% Immunoserology Peak: 8pm Dec 2016 o355 Aliquots o 50% Immunoserology o Peak: 19h

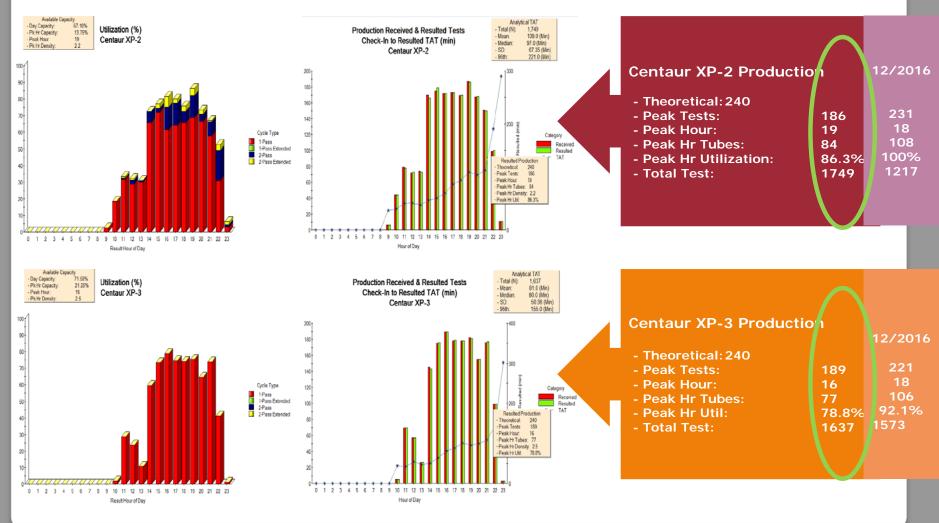
Aliquots



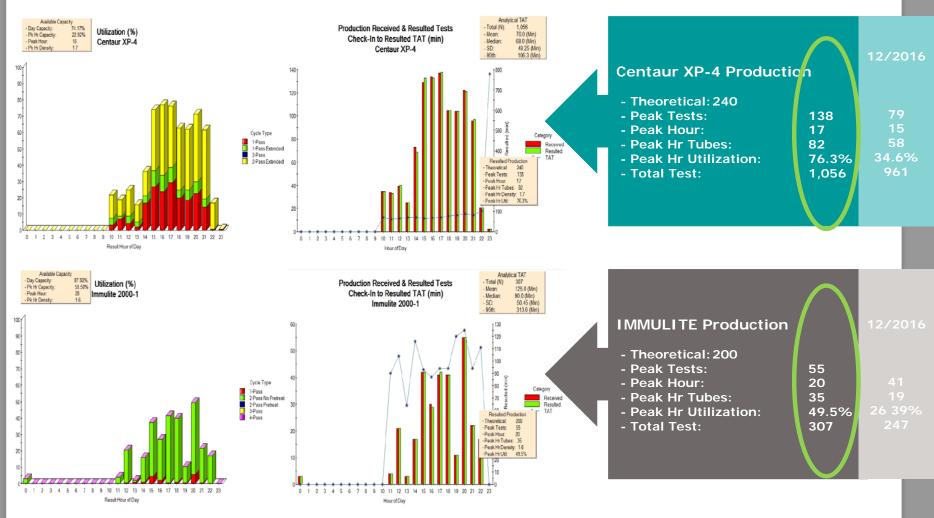
PRODUCTION DATA CAPACITY



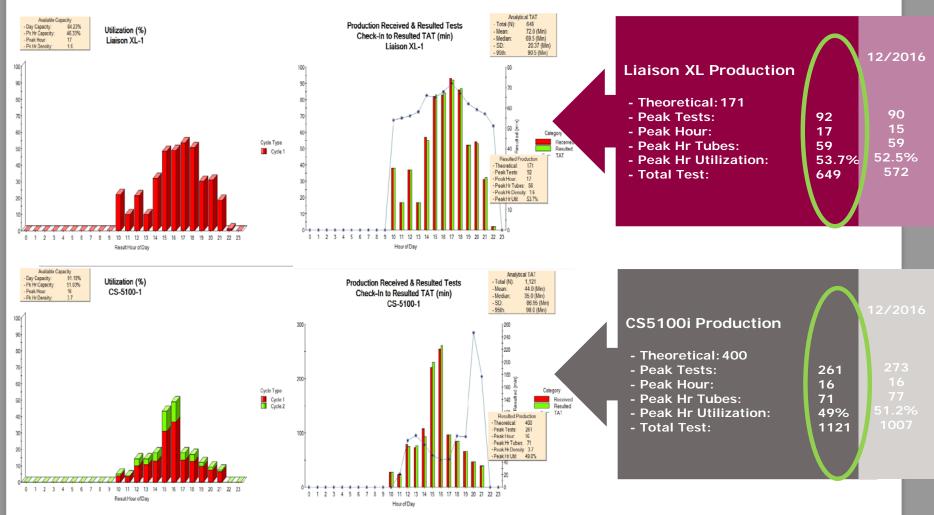
PRODUCTION DATA CAPACITY



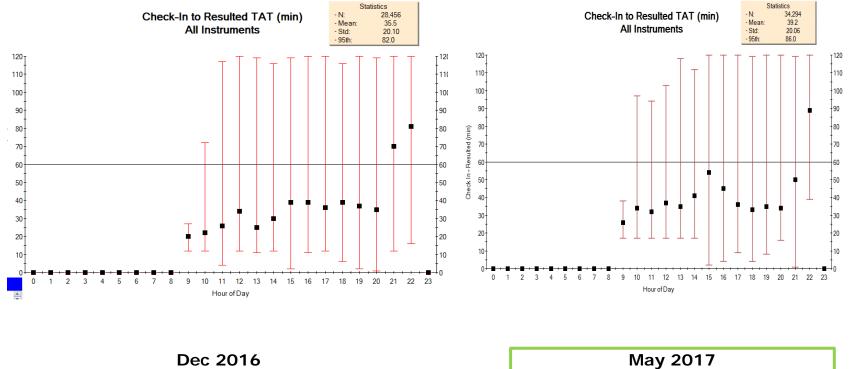
PRODUCTION DATA CAPACITY



PRODUCTION DATA CAPACITY



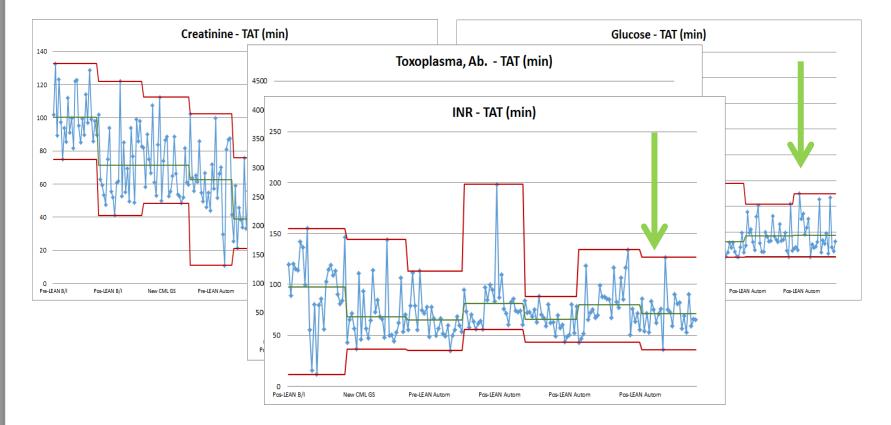
PRODUCTION DATA TAT



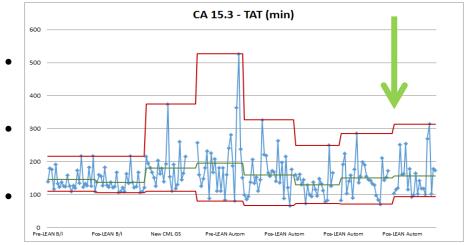
- ✓ TAT: 35.5 min
- ✓ 90 % Complete in less than 60 min
- ✓ 4.0 % re-run (4)

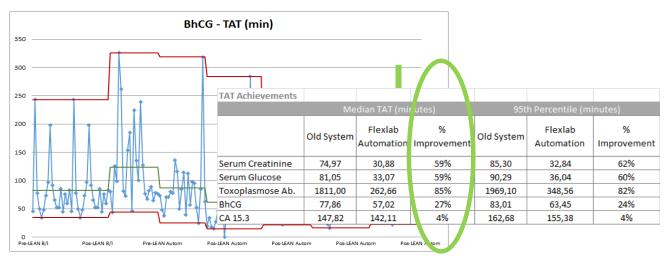
✓ TAT: 39.2 min ✓ 86 % Complete in less than 60 min ✓ 2.5% re-run (4)

PRODUCTION DATA TAT



PRODUCTION DATA





PRODUCTION DATA GROWTH

30 março 2016

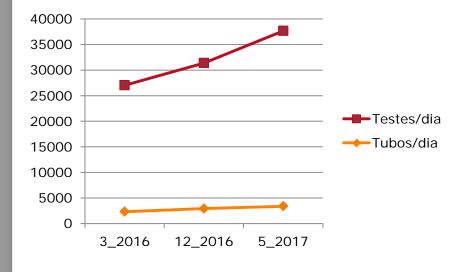
- 2,312 processed tubes
- 24,718 tests performed
- 80% serum
- 55% tubes go to 1 equipment
- Average Test / Tube: 6.5
- Peak production: 15h

5 dezembro 2016

- 2,927 processed tubes
- 28,456 tests found
- o 80% serum
- 57% tubes go to 1 equipment
- Average Test / Tube: 9.7
- Peak production: 6pm

9 maio 2017

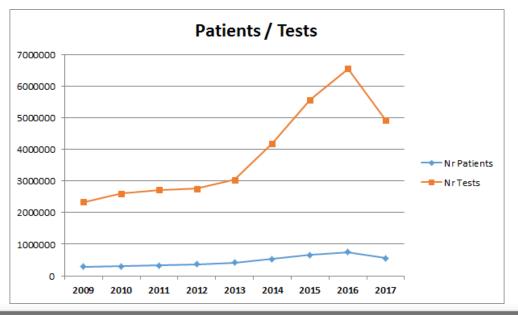
- 3,375 processed tubes
- 34,294 tests found
- o 83% serum
- o 58% tubes go to 1 equipment
- Average Test / Tube: 10.2
- o Peak production: 16h



- Average Growth: 18% per year
- Increased # tests / tube: 19%

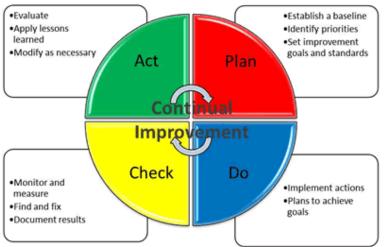
LEAN PROJECT TECHNICAL RESTRUCTURING – AUTOMATION: GOAL TO INCREASE PRODUCTIVITY

- BEFORE: Central processing lab assistants had to prioritize Promised STAT TAT: 1 hour
- o LEAN: first in; first out
- Routine < 1 hour [average: 37 min]
- o STATS only 8%
- Increase Productivity (Growth of 35% without an increase in technical costs and an increase in technical consolidation)
- Increase Traceability

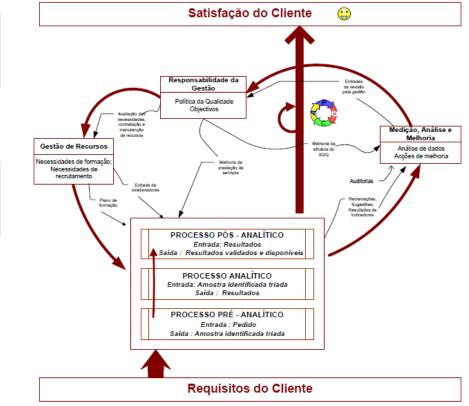


QUALITY MANAGEMENT SYSTEM

ISO 9001



- o Systematization / standardization
- o Detect error and act effectively
- Accountability of the whole team
- o Leadership
- Communication of results and improvements Team effort result



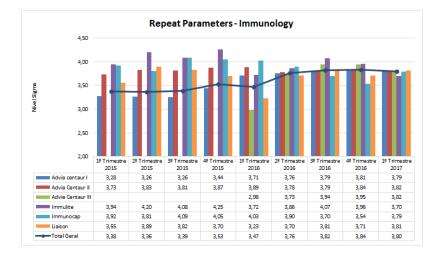
DAILY MANAGEMENT - CONTINUOUS IMPROVEMENT

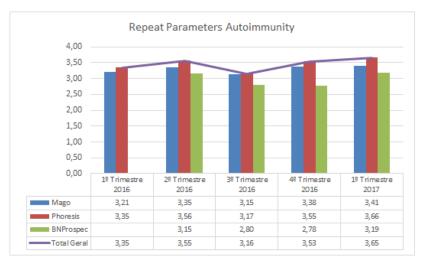
PROCESS	ACTIVITY	METRIC	METHOD OF MEASUREMENT	OBJECTIVE	PERIODICITY
				Sample Hemolysate <12%	
				Coagulated Sample <30%	
				Inadequate Proportion <5%	
	PRE- ANALYTICAL	Repetition / Reason	Sample Poorly conditioned <5%		
		/ Harvest Analysis	Poorly identified sample <10%		
				Contaminated sample <1%	
				Inadequate container <20%	
ANALYTICAL				Poorly harvested harvest <15%	Monthly
	Inscription	Incorrectly entered user data	No. of processes with demographic data changed / Total number of entries	≥ 3.5 sigma	
	Triage	Non-conforming samples	No. of non- conforming samples / Total patients	≥ 4.0 sigma	
	Analysis conference	Added / canceled analyzes	N° of analyzes added / canceled / N° patients	≥ 3.5 sigma	

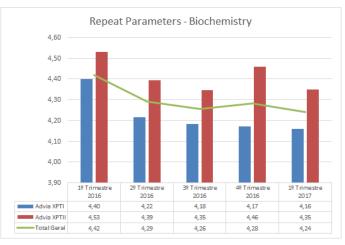
	REPEATED CROPS									
	1st Trim 2015	2nd Trim 2015	3rd Trim 2015	4th Trim 2015	1st Trim 2016	2nd Trim 2016	3rd Trim 2016	4th Trim 2016	1th Trim 2017	2nd Trim 2017
N° repetitions	169	328	468	452	539	397	424	449	515	561
Total patients	161,371	166,674	160,469	172,338	186,894	190,281	182,944	195,272	231,773	225,379
% repetitions	0.105	0.197	0.292	0.262	0.288	0.209	0.232	0.230	0.222	0.249
Sigma	4.57	4.38	4.25	4.29	4.26	4.36	4.33	4.33	4.34	4.31

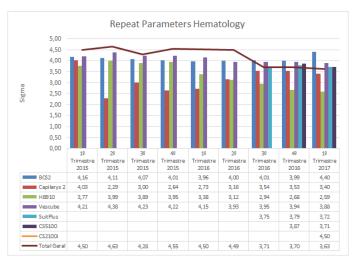
	Added / canceled analyzes							
	4th Trim 2015	1st Trim 2016	2nd Trim 2016	3rd Trim 2016	4th Trim 2016	1st Trim 2017	2nd Trim 2017	
N° of analyzes added / canceled	2317	2134	2578	2612	2895	2824	2025	
Total patients	172,338	186,894	190,281	182,944	195,272	231,773	225,379	
% defaults	1.344	1.142	1.355	1.428	1.483	1.218	0.898	
Sigma	3.71	3.78	3.71	3.69	3.68	3.75	3.87	

PROCESS	ACTIVITY	METRIC	METHOD OF MEASUREMENT	OBJECTIVE	PERIODICITY	
		Number of equipment malfunctions	Number of faults of the same type of equipment	≤ 50% of total faults	Annual	
		% Calibrations / Maintenance performed	Nr. of Calibrations / Maintenance performed / Total Planned	100%	Annual	
		Repeat Parameters	Método 6 Sigma (Nr. de resultados repetidos/ Total Parâmetros determinados)	≥ 3,5 Sigma [Por equipamento]	Quarterly	
		IQC	Analysis of the Levey- Jennings letters according to Westgard's rules	Westgard's rules [1:2s/1.3s]	Daily	
ANALYTICAL	Analytical Execution		CV analysis by parameter	CV% Table [CLIA 2010]	Monthly	
	Execution	EXecution	EQA	Previously defined with the Organization (NEQAS /	≥ 90% of analytes up to 2s	According to defined
			PANEAQ-INSA / SEQC)	≥ 60% of analyzes up to 1s	programs	
		Contaminated urine cultures	Rate of contaminated uroculture / Total number of uroculture applications	≤ 0.5%	Quarterly	
	Positive blood cultures		Positive Hemoculture Rate / Total Nr of Hemoculture Requests	≤ 8%	Quarterly	









PROCESS	ACTIVITY	METRIC	METHOD OF MEASUREMENT	OBJECTIVE	PERIODICITY
		Satisfaction index	N° of complaints / Total number of patients	≥ 4.5 Sigma	Annual
Pos- Analytical	Delivery of Results	Unconformities	Total Non-conformities / No. of patients	≥ 4 Sigma	Annual
		Delivery time	Number of Bulletins not printed (complete) in the established period / Total Bulletins	≤ 5%	Monthly

	DELIVERY TIME									
	1st Trim 2015	2nd Trim 2015	3rd Trim 2015	4th Trim 2015	1st Trim 2016	2nd Trim 2016	3rd Trim 2016	4th Trim 2016	1st Trim 2017	2nd Trim 2017
Nr defaults	2765	4461	2419	3558	1684	1834	1401	1031	1254	1030
Total patients	161,371	166,674	160,469	172,338	186,894	190,281	182,944	195,272	231,773	225,379
% defaults Delivery time	1.713	2.676	1.507	2.065	0.901	0.964	0.766	0.528	0.541	0.457
Sigma	3.62	3.43	3.67	3.54	3 86	3.84	3.92	4.06	4.05	4.10

LEAN – FLEXLAB AUTOMATION

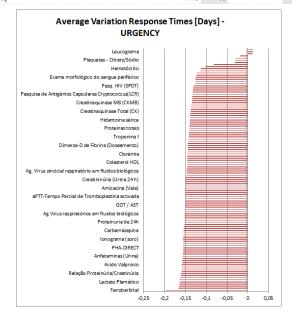
				SATISF	ACTION INE	DEX				
	1st Trim 2015	2nd Trim 2015	3rd Trim 2015	4th Trim 2015	1st Trim 2016	2nd Trim 2016	3rd Trim 2016	4th Trim 2016	1st Trim 2017	2nd Trim 2017
N° of complaints	1	3	4	6	14	20	17	8	15	15
Total patients	161,371	166,674	160,469	172,338	186,894	190,281	182,944	195,272	231,773	225,379
% complaints	0.001	0.002	0.002	0.003	0.007	0.011	0.009	0.004	0.006	0.007
Sigma	5.87	5.63	5.56	5.48	5.29	5.20	5.23	5.44	5.32	5.32

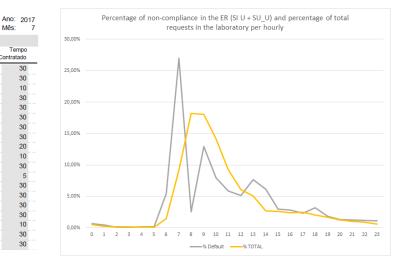
DAILY AUDIT: TAT MEASURED AS % MEETING TARGET

Mês:

Average TAT – Emergency service

Parameter	Serviço Urgênc	ia (URG)	Serviço Urgência (ROT)	Tempo
	Quant	Tempo	Quant Tempo	Contratado
Acido Valproico	3	18		30
Albuminémia [Albumina sérica]	55	9		30
aPTT-Tempo Parcial de Tromboplastina activada	755	8		10
Benzodiazepinas (Pesquisa na Urina)	4	5		30
Carbamazepina	1	3		30
Creatinaquinase Total (CK)	476	10		30
Creatinina sérica [Creatininémia]	1.839	11		30
Desidrogenase Láctica-LDH (Soro)	954	11		30
Dímeros-D de Fibrina	132	14		20
Fibrinogénio [Factor I]	43	10		10
Fosfatase Alcalina [ALP]	770	12		30
Gasimetria	78	3		5
GGT (Gama-Glutamil -Transpeptidase)	1.018	12		30
Glicémia em jejum	785	11		30
GOT / AST [Aspartato Aminotransferase]	1.394	12		30
GPT / ALT [Alanina Aminotransferase]	1.334	12		30
Hemograma com Plaquetas	2.281	8		10
lonograma sérico	1.789	11		30
Lipasémia [Lipase sérico]	148	16		30





TAT daily control

STAT analyzes and verification 0 of compliance with contracted times in the different Hospital laboratory units.

IN THE VANGUARD OF KNOWLEDGE

The Germano de Sousa Group today is much more than simply a network of Clinical Pathology Laboratories. It is also a research centre and a partner for professional colleagues, with whom it shares clinical and technological knowledge in a wide variety of ways.

RESEARCH

Development of various areas of research, the most recent being:

- Genetics
- Autoimmunity
- Molecular Biology
- Oncological Diagnosis

HOSTING AND PARTICIPATION IN WORKSHOPS

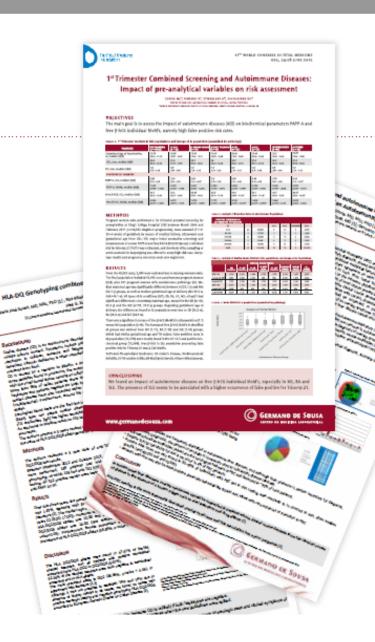
TRAINING AND EDUCATION

The Germano de Sousa Group, in partnership with the NOVA University of Lisbon - NOVA Medical School, and with Universidade Católica Portuguesa, teaches on Postgraduate and Integrated Master's courses.

PRODUCTION AND DISSEMINATION OF SCIENTIFIC INFORMATION

- Scientific Posters
- Newsletter
- Scientific Brochures
- Active Participation

in International Research Groups





Plataforma genômica para identificação de biomarcadores na Leucemia Linfocítica Crónica (LLC)

It candi recompte fai platituria di slige-strat postati ne providi technica opticaria se attestigan checi danam-ne se provine partigio tecche moltigio. lo devento consume con constitución posteligante de devento constitución e constitución de servera enterestica de la devento constitución de servera enterestica de la devento constitución de servera enterestica de la devento de servera enterestica del servera enterestica de la devento de servera enterestica de la devento de servera enterestica de servera enter A full-blacke genternal semantale (2.6) i anticiperent specific rada i menorettiga hari officere sa tarettiligali da, preciaer the scheroster as an even of a list. Name And Address and the propriet of the lot detrochades that anythe y drighter, their substrangement relation and their filingly instrumble Parameterizations if any investigabilities Résolution de la faire et monograficamente du la comparti porte la compartica distantion generation over a difficient of the temperature (viter Co. Server Col) 4 (g) to Equation and Imported two polar scherings data your worket from the content of a more schering of the couple society. A memory is index or spanning in the polarity of 18, 9 D Genericki multi in one technik ka titren constituate Ringemuit, contained o Citi i prestante satuter kas DPs. Distances I parties is into press 16.00 Mary Louisiday Base di sagior perfitivato per associativa da per transformata per, di peperado menechasi de Distatua (1988) p." Il propriori da tal 2 nucheri, enciente famadares per ante advante la abrangari magnante famigari. La primatorine un elementarente per persona da tanga ? + - Innershi di Ind = -447.4 A SECURITY OF THE * 30Y CONTINUES SETTING. ALL MAN requiring the common Municipal and Conference on The ut, destaurantege o planetikeje de genetike, de kolon jad s In planning to 27 liver on requirements and a cost home-menter en presia con divisió altar amendica, so en visible montaña, el casis, con a decisio non tamma de antañamento ner menne krephten is til des some a mitele figter Reveluterburgt, administrationers anderen figter which and a local data which

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LESSONS LEARNED - TRAINING ACADEMY

Periodic visits of the employees of the stations to the Laboratory: involvement of the teams and perception of the impact of the error

Individual and group performance evaluation - merit award

Training plan, diversified and meeting the needs of the group

Round Tables "From everyone to everyone"

Internal Customer satisfaction surveys

LESSONS LEARNED – MILESTONES & PRIORITIES

- Redesign core lab leaner and more flexible
 - o Requires substantial leadership and financial investment
- Rapid Process Improvement Workshops in all sections
- Facility design for lean
- Frontline point improvements
- Integration of quality, auditing, corrective action
- o Cultural Change to Lean Six Sigma Thinking
 - Listening to people ideas-toimprovements work
 - Involvement of people in Lean work, learn by doing
 - Focus on what really matters the customer
 - o 5S
 - o Standardization
 - o "Check-Act" after you "Plan-Do"
 - o Continuously achieve ISO 9001 concept







THE CHANGE BEGINS WHEN SOMEONE SEES THE NEXT STEP

Scientific academy

- o Consolidate education
- Increase the scientific publications of our work
- Increase as partnerships with educational institutions (colleges and institutes) - transmission of knowledge

Sustainable culture

- Consolidate new laboratory in North Country
- Full-automation
 of hematology in Flexlab
- Increase new equipment in Flexlab



ANTICIPATING THE FUTURE ON THE SHOULDERS OF THE PAST

NEXT STEPS



City by the sea, with waves that break against the walls, admirable and where history whispers. The western part of the city is surmounted by superimposed arches resting on marble columns. By nature, the city is beautiful.

You're welcome





QUESTIONS?

THANK YOU!

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A CONTRIBUIÇÃO DO LABORATORIO MEDICO É FUNDAMENTAL PARA UM RÁPIDO DIAGNOSTICO

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