CASE STUDY

Lean-Sigma Lab Space Redesign Results in 50% Improvement in Efficiency and Average 40% Faster Turnaround Time

The laboratory at a 330-bed tertiary care facility and world-class research center, located in Eastern Canada, handles 6.5 million tests a year with 138 full-time employees. With a wide range of services, including rapid response testing, specialized micro-volume analysis and sub-specialty pathology and lab medicine services, it also functions as a national reference center and supports research and clinical trials. Nonetheless, only modest growth was realized in most areas of the lab due to physical space constraints and limited resources.

The Challenges

- Expansion of other departments and subsequent space reconfiguration for the pediatric operating rooms resulted in the loss of over half of the current lab space
- Possible transfer of portions of the lab to multiple or separate locations
- Inadequate layout of current laboratory work stations contributed to inefficient workflow
- Redesign the current work space to accommodate smaller space allocations
- Increase efficiency, minimize operating expenses and improve patient service

The Solution

Combining the rapid process improvement methodologies of Lean and Six Sigma in real time, the laboratory partnered with the client to:

- Assess current workflow and develop value stream maps of present and future configurations
- Consider new technology, equipment, facility changes, and testing requirements for each lab section
- Identify process improvement opportunities
- Redesign lab processes to remove waste, reduce error, and optimize workflow patterns and associated equipment locations
- Design a new physical layout adapted to the redesigned workflow
- Train key staff on Lean methodologies and conduct a Lean pilot

The Results

The lab achieved the following:

- Educate the staff on Lean-Sigma methodologies to sustain improvements and drive new opportunities.
- Lean-Sigma pilot project in the Blood Bank demonstrated rapid improvement in workflow with a **50% reduction in technologist movement** in the testing area.
- Design physical space layouts for new and remodeled areas to improve specimen flow and allow for anticipated and unanticipated growth — **savings of $215,000.**
- Streamlined processes in the new work space resulted in an **average 40% faster turnaround time** and improved customer satisfaction.
- Application of 5S methodology in the entire lab to reduce clutter and remove nonfunctioning (non-value added) materials.

CASE STUDY

Using Lean-Sigma, Lab Speeds ED Testing by 50%, Increases Productivity by 40%, and Reduces Space Needs up to 30%

The clinical laboratory at a large community hospital in Northern California (USA) that provides primary and secondary levels of care, including a cancer and heart institute and Level III Trauma Center, faced operational challenges that negatively impacted customer satisfaction and patient care, as well as staff efficiency.

The Challenges

The hospital's clinical laboratory processes 260,000 tests annually, with an operating budget of $3.5 million and 63 full-time employees. Operational challenges include:

- Lengthy turnaround times for STAT orders from the Emergency Department (ED)
- Multiple processes for executing routine and STAT orders
- Inefficient workflow for pre-analytical specimen processing
- Expensive/noncost-effective testing
- Inadequate work station configuration that negatively affected workflow efficiency
- Questions on architectural design and planned modifications of the physical space

The Solution

Using Lean-Sigma process improvement methodologies, the laboratory prioritized and implemented initiatives to deliver measurable results within specific timelines and resource constraints by:

- Training key staff on the principles and tools of Lean-Sigma to garner staff support and ensure meaningful and sustainable change
- Developing rapid improvements in the pre-analytical, analytical and post-analytical processes (specifically, chemistry, hematology, urinalysis and coagulation) to enhance turnaround time to the ED
- Educating key non-lab staff to gain support of process changes and foster relationships between the lab and other departments
- Designing a control plan for long-term sustainability
- Providing guidance on reconstruction plans to validate feasibility and maximize efficiency

The Results

The lab achieved significant qualitative and quantitative impact including:

- **50% improvement** in ED test delivery and throughput. Time from receipt to result was reduced from 45 minutes to 22 minutes.
- **95% of morning lab work completed by 8 am**—significantly improved from pre-project goal of 72%-75%.
- **40% improvement in productivity** resulted in increased capacity to grow outreach testing services by over **$500,000 per month in net revenue.**
- Consolidation of routine testing resulted in **$390,663 annualized savings.**
- Daily overtime reduced by two hours per day—**a savings of $160,000.**
- **20%-30% reduction** in space requirements.
- Improved patient, customer, and staff satisfaction.

CASE STUDY

Lean Blitz Speeds Patient Registration and Phlebotomy Collection, 73% Improvement in Throughput and 70% Decrease in Wait Time

A regional reference laboratory, operating 2 hospital laboratories and 22 patient service centers located in the Southeast (USA) values local service and quality results. The philosophy of the laboratory has always been that each patient deserves the best care and the most responsive test results possible. However, they faced operational challenges in the patient registration and blood collection area that negatively impacted their ability to deliver optimal customer service.

The Challenges

Patient flow challenges included:

- By the lab's 7:00 am opening time, 16 patients in the queue for registration in numerical order
- Excessive wait times (average registration wait time of 120 minutes) with frequent patient complaints
- On average, 20 patients waited for blood collection between 7:00 am and 9:00 am
- Non-standardized methods for patient registrations that required changes in medical record history
- Inefficient workflow; patients spent additional time post registration waiting for the phlebotomist to collect blood
- Preferential treatment for patients with standing orders (e.g., assisted before those with assigned numbers)
- Staff was unable to take scheduled breaks before 11:30 am due to the high number of patients for blood collection
- Due to the backlog of patients, the 5:00 pm closing time was rarely accomplished; this contributed to overtime costs for the lab and frustration for staff
- Special kits/supplies for clinical trials were not available in the blood drawing areas, resulting in interruption of the collection process to gather supplies
- Supplies in the drawing areas often depleted during peak times, adding time for re-stocking
- Copiers were unavailable in each registration area, requiring staff to interrupt the process to make copies in another area

The Solution

By employing Lean rapid process improvement methodologies during a two-day period, the laboratory prioritized and implemented initiatives to deliver fast, measurable results.

- Through process observation, recommended plan for data collection with design and implementation of Lean pilots for process changes:
  - Established greeter to review order and process patients (e.g., assignment of green cards for simple registrations, yellow cards for complex registrations)
  - Assisted patients in sequence by a designated process
  - Standardized work station layout
- Provided short- and long-term suggestions to maintain process changes:
  - Defined target results (e.g., monitor wait/registration times, maintain green card process in single piece flow, transport bulk of specimens at scheduled pick-up times)
  - Obtained staff feedback; encouraged communication
  - Sustained patient satisfaction

The Results

After implementing Lean improvement methods, this laboratory achieved significant qualitative and quantitative results, including:

- 73% increase in phlebotomy registration and throughput.
- 70% average reduction in patient wait times.
- Enhanced patient and employee satisfaction.
- Improved specimen flow—more specimens sent to the core lab for processing with the first courier pick-up.
- By 11:00 am, 7% more patients had been processed through the system than the prior day, without requiring additional resources.

CASE STUDY

Lean Sigma Urinalysis Solutions Results in 0.5 FTE capacity gain, 26% Decrease in Turnaround Time, 28% Improvement in Specimen Quality, and 4.1% Reduction in Total Cost-in-Use

A 577 bed, nationally recognized facility for cardiac, orthopedic, neonatal intensive care and home healthcare programs located in the Northeast (USA) conducts 3.5 million lab tests per year. The Center's focus on total quality management has driven continuous improvement efforts for the laboratory. A comprehensive urinalysis solution was implemented that consisted of workflow and process enhancement initiatives, incorporation of automation, and a closed urine collection system.

The Challenges

In a typical day, the laboratory manages more than 145 urinalysis tests and about 70 cultures from their outpatient clinics, nursing floors, and physician offices. Opportunities for improvement in several aspects of the testing process were identified:

- Efficiently managing increase in urinalysis workload
- Inability of the existing testing processes and workflow to handle specimen demand (particularly during peak hours)
- Improve turnaround time for specimens from the Emergency Department (67% of urinalysis workload)
- Decrease number of false positive urine cultures
- Improve *Receive to Verify* times (Laboratory ranked in the 9th percentile versus a similar peer group)
- Decrease staff movement when obtaining urine cultures
- Prepare for CMS' upcoming reimbursement changes due to be implemented in October 2008

The Solution

By incorporating Lean-Sigma process improvement methodologies, the installation of an automated system, and the urine collection system, this medical center maximized the testing efficiency and workflow within its laboratory.
This process included:

- Identifying segments of the process that demonstrated inadequate performance as well as those that warranted a detailed examination
- Assessing productivity based on hands-on operator time using cycle time measurements
- Measuring one of the fundamental goals of Lean process improvement—reduction in the length of time from order to delivery
- Quantifying defects (e.g., leaking specimens, outliers) as a means of eliminating waste
- Training Urinalysis Department staff on Lean principles (e.g., single piece flow, standardization of processes)
- Replacing existing manual microscopy and urine chemistry equipment with a complete automation system; relocate equipment for more convenient access to the point of specimen entry to the laboratory
- Implementing a closed urine collection system to safely transport urine, decrease false positives, and eliminate re-testing

The Results

The laboratory experienced significant qualitative and quantitative progress including:

- Ability to handle total urinalysis workload—at any time of the day or night—without delay.
- **Overall turnaround time decreased by 26% in all areas**; with ED turnaround times decreased by 21%.
- Reduced inquiries from nursing staff on specimen status and recalls—possible **labor savings of $100,000** per year.
- Technical staff requirement decreased by 50%, translating into a **productivity and capacity gain of 0.5 FTE**, allowing redeployment of staff to perform other functions.
- As a result of the Lean layout and automated urinalysis, **staff movement was reduced by 61%.**
- Lower proportion of outliers—specimens with turnaround time above 2 hours dramatically decreased in the ED and inpatient locations.
- Improvement in specimen quality with a **28% decrease in poor quality urine culture specimens** – mixed growth.
- **4.1% reduction in total cost-in-use** for urinalysis and urine culture processes (which are related to the initial urine collection process).

Tech Talk®

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Author: Nayana Patel

Q. What are the preanalytical variables that can affect urinalysis test results?

A. Preanalytical factors such as specimen collection, specimen handling, specimen integrity, interfering substances and patient factors are common causes of inaccurate test results. Improper specimen collection and processing can influence the outcome of analytical results. By minimizing errors at any step in the preanalytical phase, a laboratory can improve the quality of analytical results, reduce the number of re-collected specimens, and improve turnaround time and patient management.

Physical Examination of Urine:

Color and clarity can be measured either visually or by an analyzer.

Color:

The color of urine, which is normally colorless or one of the various shades of yellow, can be altered by medications, vitamins, dyes or diet. If an unusual color is detected for the urine specimen, one of these conditions could be the cause.[1]

One of the most common causes of abnormal color is the presence of blood. Non-pathogenic causes of red urine include menstrual contamination, ingestion of highly pigmented foods and medications. Ingestion of blackberries and beets may redden the urine. Phenol derivatives found in certain intravenous medication produce green urine on oxidation. A purple staining may occur in catheter bags and is caused by the presence of indican in the urine or a bacterial infection, frequently caused by *Klebsiella or Providencia species*.[2] The abnormal urine colors can affect other dipstick results by causing colorimetric reactions that may be misinterpreted by the instrument and give incorrect results.[1]

Clarity:

A normal urine specimen is typically clear. Urine clarity can be related to the handling conditions of the specimen. If a urine specimen is old and unpreserved, it can become cloudy from bacterial overgrowth. In turn, if a specimen has been stored in a refrigerator, amorphous urates or phosphates can cause temporary cloudiness (which dissolve when the specimen is brought to room temperature). The collection time and storage conditions of the specimen should be reviewed to determine if cloudiness may be caused by storage conditions.[1] Additional nonpathogenic causes of urine turbidity include semen, fecal contamination, radiographic contrast media, talcum powder, mucus, crystals, leukocytes, epithelial cells, fat globules and vaginal creams.[1,2] Similar to abnormal coloration, a lack of clarity may lead to test result inaccuracies. The turbidity of urine should be recorded and microscopically explained.[3]

Chemical Examination of Urine:

Typical urinalysis dipstick tests include: pH, protein, blood, nitrite, leukocyte esterase, glucose, ketones, urobilinogen, bilirubin and specific gravity.

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The following table will review some of the preanalytical variables that can contribute to false-positive and false-negative results. Please note that the effect of these variables will vary according to the type of test strip used.

Urinalysis Dipstick Tests:

Preanalytical Variables

Test	False-positive	False-negative
pH	No interferences known[2]	No interferences known2
Protein	After strenous exercise[1]	Exposure to extreme heat or cold, dilute specimens, fever, mental stress, mucus[1]
	Highly buffered or alkaline urine[2]	Proteins other than albumin, Microalbuminuria[2]
	Pigmented specimens[2]	
	Antiseptic, chlorhexidine[2]	
	Loss of buffer from prolonged exposure of the reagent strip to the specimen[2]	
	Quaternary ammonium compounds (detergents)[2]	
	High specific gravity[2]	
	Highly colored substances that mask results, such as drugs (phenazopyridine)[2]	
	Improperly preserved specimen[6]	
Blood	Consumption of colored medications[1]	High specific gravity/crenated cells[2]
	Presence of chlorine bleach[1]	Formalin[2]
	Menstrual contamination[2]	Captopril[2]
	Strong oxidizing agents[2]	High concentrations of nitrite[2]
	Bacterial peroxidases[2]	Ascorbic acid >25 mg/dL[2]
		Unmixed specimens[2]
Nitrite	Colored medications and dyes[1]	Nonreductase-containing bacteria[2]
	Improperly preserved specimens[2]	Insufficient contact time between bacteria and urinary nitrate[2]
	Highly pigmented urine[2]	Lack of urinary nitrate[2]
	Beet digestion6	Large quantities of bacteria converting nitirite to nitrogen[2]
	Highly colored substances that mask results, such as drugs (phenazopyridine)[6]	Presence of antibiotics[2]
		High specific gravity[2]
		High concentrations of ascorbic acid[2]
Leukocyte esterase	Contamination by oxidizing agents and detergents, formalin[1]	High specific gravity[1]
	Highly pigmented urine, nitrofurantoin[2]	High concentrations of protein, glucose, oxalic acid, ascorbic acid[2]
	Highly colored substances that mask results, such as drugs (phenazopyridine)[6]	Drugs such as gentamicin, cephalosporins, tetracyclines and inaccurate timing[2]
	Beet digestion[6]	Strong oxidizing agents (soaps and detergents)[6]
	Vaginal contamination of urine[6]	
Glucose	Improper storage of reagent strips, when exposed to air[1]	Drugs such as tetracycline[1]
	Contamination by oxidizing agents and detergents[2]	Low temperatures[2]
	Peroxide contaminants[6]	High levels of ascorbic acid, ketones, specific gravity[2]
		Improperly preserved specimens[2]

Urinalysis Dipstick Tests: Preanalytical Variables		
Test	**False-positive**	**False-negative**
Ketones	Highly pigmented red urine, medication containing free sulfhydryl groups[2]	Improper storage, resulting in volatilization bacterial breakdown[6]
	Atypical colors with phenylketones and phthaleins[6]	
	Large amounts of levodopa metabolites[6]	
Urobilinogen	Colored medications[1]	Specimen exposure to light[1]
	Porphobilinogen[2]	High level of ascorbic acid[1]
	Indican[2]	Preservation in formalin, old specimens[2]
	p-aminosalicylic acid[2]	High concentrations of nitrate[2]
	Sulfonamides[2]	Improper storage, resulting in oxidation to urobilin[6]
	Methyldopa[2]	
	Procaine[2]	
	Chlorpromazine[2]	
	Highly pigmented urine[2]	
	Beet ingestion[6]	
	Highly colored sustances that mask results, such as drugs (phenazopyridine)[6]	
Bilirubin	Colored medications[1]	Specimen exposure to light[2]
	Highly pigmented urines[2]	Ascorbic acid >25 mg/dL[2]
	Metabolites of Iodine[2]	High concentrations of nitrite[2]
	Drug induced color changes such as phenazopyridine, indican-indoxyl sulfate[6]	Improper storage, resulting in oxidation or hydrolysis to nonreactive biliverdin and free bilirubin[6]
	Large amounts of chlorpromazine metabolites[6]	
Specific Gravity	High concentrations of protein[2]	Highly alkaline urines (>6.5)[2]
	Ketoacids such as lactic acid, ketones[6]	Glucose and urea concentration > 1 g/dL[6]

Microscopic Examination:

Because of changes that occur in unpreserved urine, specimen collection and storage strongly affect what formed elements are observed during the microscopic examination.[4] Unpreserved specimens that have been unrefrigerated for more than 2 hours from time of collection should not be accepted for microscopic analysis due to the increase in bacterial overgrowth and the disintegration of cells and casts. The urine becomes alkaline, causing red blood cells and white blood cells to lyse and casts to dissolve.[1]

Refrigeration for up to 48 hours usually prevents the degeneration of cells and pathological entities, but it can increase the precipitation of amorphous phosphates and urates, which may obscure the microscopic sediment analysis.[2,3] If a specimen has been refrigerated for storage, it should be allowed to come to room temperature and mixed well prior to analysis. Amorphous urates or phosphates develop in cold conditions and will affect the analysis. Contaminants that can be seen during sediment analysis include mucus, spermatozoa, fibers, talcum powder and oil. It is important not to confuse these contaminants with cellular components.[1]

Many crystals are induced by various medications. Some bacteria may be present because of contamination during collection or prolonged storage. The presence of parasites in urine usually indicate vaginal or fecal contamination.[3]

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Flow cytometry is another method of examining the urine for microscopic elements. This method of microscopic analysis, however, is almost unaffected by preanalytical variables. The factors that could affect flow cytometry test results may be underfilling preservative tubes or insufficient mixing of the specimen.[1] Please refer to your instrument company for additional information.

Proper specimen handling, integrity and preservation:

According to CLSI (Clinical and Laboratory Standards Institute) guidelines, a urine specimen should be analyzed as soon as possible after arrival in the laboratory.[5] Generally, after standing two hours at room temperature, the chemical composition of urine changes and formed elements begin to deteriorate. Urine constituents, such as bilirubin and urobilinogen, are unstable. Bacteria can alter glucose concentration, and pH changes can occur if the urine is allowed to stand. For specimens not analyzed within 2 hours of collection, preserve the urine specimen using refrigeration or a specifically designed chemical preservative.[5] A variety of urine preservatives are available that allow urine to be kept at room temperature while still providing results comparable to the refrigerated urine.

A urinalysis preservative tube with a conical bottom is designed to prevent the overgrowth of bacteria and maintains the urine sample integrity for up to 72 hours at room temperature for urinalysis testing. Without the presence of a preservative, the bacteria continue to metabolize and reproduce, causing changes in the urine chemistry components measured in a routine urinalysis.[7] An evacuated tube system is designed to achieve proper fill volume to ensure the proper specimen-to-additive ratio and also reduce the potential exposure of the healthcare worker to the specimen. The proper specimen-to-additive ratio must be maintained when using a chemical preservative to ensure accurate test results. Maintaining the correct ratio is especially important when transferring samples to a preservative tube. Underfilling or overfilling containers with preservatives may affect specimen-to-additive ratios. Underfilling the tube will leave a high concentration of preservative in the specimen, while overfilling the tube will dilute the preservative. In either case, the function of the preservative may be compromised.[8]

Inverting the tube 8-10 times ensures the incorporation of the spray-coated preservatives with the urine sample. Insufficient mixing or not mixing the tube after the urine sample is drawn into the tube may result in an improperly preserved sample.[7]

By minimizng the preanalytical influences during specimen collection and handling, a suitable specimen can be obtained. Specimen handling is probably the most important step in obtaining a good urine specimen that can provide the most useful clinical information. It is also important to carefully record any details that may be beneficial in the interpretation of the urine results. After all, the results are only as good as the specimen collected.

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Tech Talk

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Author: Lena Arzoumanian

What Is Hemolysis?

Hemolysis is the breakage of the red blood cell's (RBC's) membrane, causing the release of the hemoglobin and other internal components into the surrounding fluid. Hemolysis is visually detected by showing a pink to red tinge in serum or plasma.[1] Hemolysis is a common occurrence seen in serum samples and may compromise the laboratory's test parameters. Hemolysis can occur from two sources:

- *In-vivo* hemolysis may be due to pathological conditions, such as autoimmune hemolytic anemia or transfusion reaction.[1]
- *In-vitro* hemolysis may be due to improper specimen collection, specimen processing, or specimen transport.

What Are The Causes?

Specimen Collection:

Evacuated Tubes

- An improper choice in the venipuncture site, such as drawing from a distal site to the antecubital region of the arm rather than drawing from an antecubital site, has been shown to result in more hemolysis.[2]
- Prolonged tourniquet time causes the interstitial fluid to leak into the tissue and cause hemolysis.[2]
- Cleansing the venipuncture site with alcohol and not allowing the site to dry may cause hemolysis.[3]
- An improper venipuncture, indicated by a slow blood flow, may indicate occlusion due to the lumen of the needle being too close to the inner wall of the vein, causing hemolysis.[4]
- The use of a small-bore needle, resulting in a large vacuum force applied to the blood, may cause shear stress on the red blood cells, causing them to rupture.[1,5,6]
- The use of a large bore needle may result in a much faster and more forceful flow of blood through the needle, resulting in hemolysis.[1,7]

Syringe Draws

- Pulling the plunger of a syringe back too far while using a large bore needle, may cause enough pressure for hemolysis to result during collection. The pressure may be greater than a standardized evacuated tube.
- Transferring into a tube by pushing down on the syringe plunger in order to force blood into a tube may cause hemolysis, as well as create a positive pressure in the tube which may cause the stopper to come off.

IV Catheters

- Several studies have noted that when blood is drawn from a peripheral IV catheter, a higher incidence of hemolysis occurs due to frothing of the blood from a loose connection of the blood collection assemblies.[1,8]

Specimen Processing:

- Vigorous mixing or shaking of a specimen may cause hemolysis.
- Not allowing the serum specimen to clot for the recommended amount of time can result in fibrin formation in the serum. The use of applicator sticks to dislodge the fibrin may cause rupture of RBC's, resulting in hemolysis.[1,5]
- Prolonged contact of serum or plasma with cells may result in hemolysis.[9]
- Exposure to excessive heat or cold can cause RBC rupture and hemolysis.[10]

Specimen Transport:

- Mechanical trauma during transport may occur with the use of a pneumatic tube system, resulting in hemolysis. Variable factors associated with the system are related to system differences such as length, speed, and number of times the specimen is transported, as well as the number of angles or turns the system uses.[2]

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What Are The Effects Of Hemolysis?

Test results from all laboratory disciplines can be affected by hemolysis, especially in chemistry. Hemolysis may cause certain analytes to be increased due to leakage of red cell constituents (e.g., lactate dehydrogenase and potassium), or may cause interference in the test method (e.g., spectrophotometric methods). The amount of interference will depend on the degree of hemolysis and on the specific test method being used. Hemolysis is a common cause of specimen rejection in laboratories, which requires the specimen to be redrawn.[5,10,11,12,13]

Corrective Actions

- **Redraw the specimen.**
- **The most common sites to draw from are the median cubital, basilic, and cephalic veins from the antecubital region of the arm.**
- **The choice of the needle gauge size is dependent on the patient's physical characteristics and the amount of blood to be drawn. Avoid using a needle that is too small or too large.**
- **The tourniquet should be released after no more than one minute, and excessive fist clenching should be avoided.**
- **Without touching, allow the venipuncture site to air dry.**
- **Avoid drawing the syringe plunger back too forcefully when collecting blood with a needle and syringe.**
- **Avoid pushing the plunger too forcefully when transferring to a tube. Use a blood transfer device when transferring from a syringe to a tube without pushing the plunger.**
- **Ensure all blood collection assemblies are fitted securely, to avoid frothing. Utilize a luer-locking device with infusion equipment to ensure a secure fit.[14]**
- **Gently invert the blood collection tube and mix additive specimens thoroughly according to manufacturers' recommendations.**
    - **Invert specimen with a clot activator 5 times to ensure the distribution of the clot activator within the sample, and allow the specimen to clot for a full 30 minutes in a vertical position.**
    - **Non-gel serum tubes should be allowed to clot for 60 minutes in a vertical position.**
    - **Sodium citrate tubes for coagulation testing should be inverted 3-4 times.**
    - **All other anticoagulant tubes should be inverted 8-10 times.[3]**

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