Microbiological Stability Assessment of Municipal Distribution Line Using Control Chart Approach for Total Bioburden Count / *Toplam Biyolojik Yük Miktarı için Kontrol Çizelgesi Kullanılarak Belediye Dağıtım Hattının Mikrobiyolojik Stabilitesinin Değerlendirilmesi*

Mostafa ESSAM EISSA[1], Engy REFAAT RASHED[2], Dalia ESSAM EISSA[3]

Cairo University, Faculty of Pharmacy (independent Researcher Category), Cairo, Egypt, mostafaessameissa@yahoo.com

Engy REFAAT RASHED, National Centre for Radiation Research and Technology, Cairo, Egypt, engyrefaat@yahoo.com

Dalia ESSAM EISSA, Royal Oldham Hospital, Oldham, United Kingdom, eissade@yahoo.com

Gönderim Tarihi | Received: 13.12.2021, Kabul Tarihi | Accepted: 26.02.2022, Yayım Tarihi | Date of Issue: 1.08.2023

Atıf | Reference: "ESSAM EISSA, M., REFAAT RASHED, E., ESSAM EISSA, D. (2023). Microbiological Stability Assessment of Municipal Distribution Line Using Control Chart Approach for Total Bioburden Count. *Health Academy Kastamonu (HAK)*, 8(2), s.363-383. DOI: https://doi.org/10.25279/sak.1035879"

Öz

Arka plan: Belediye suyunun mikrobiyolojik kalitesi, insan faaliyetleri, tüketimi ve sonraki işlemler için güvenli kabul edilebilir suyun teslim edilmesini sağlamak için dikkatle izlenmesi ve kontrol edilmesi gereken önemli bir denetim özelliğidir. Vaka sunumu: Mevcut vaka, bir sağlık tesisinde farklı kullanım noktalarından su dağıtımına ilişkin uzun vadeli veri eğilimlerinin incelenmesi ve analizi için özel bir nitelik kontrol çizelgesi türünün uygulanmasını göstermiştir. Tüm veri kümeleri, Spesifikasyondan gözlemlenebilir sapmalar (OOS) olmaksızın tek aralıklı yüksek değerlere işaret eden, sağa çarpık bir veri dağılım modeli gösterdi. Hiçbir su hattı, normalliği iyileştirip veri kümelerinden aykırı değerleri kaldıracak dönüşüme ihtiyaç duymadan, bilinen herhangi bir dağıtım modelini takip edemedi. Mikrobiyolojik sonuçların kaydını görselleştirmeye yönelik doğrudan yaklaşım, Laney öznitelik çizelgeleri kullanılarak gerçekleştirilmiştir. Tartışma: Her kullanım noktası; ortalamayı, düzeni, Üst Kontrol Limitini (UCL) ve alarm türlerini görselleştirerek kendine özgü veri eğilimine sahipti. Tesisteki su dağıtım sisteminin net kalitesi, ortalaması alınan ve tek bir süreç-davranış çizelgesinde bir araya getirilen genel okumalardan çıkarılabilir. Bu eğilim grafiğinin uygulanması, olası mevsimsellik belirtileriyle birlikte genlikte tutulma eğiliminde olan biyolojik yük sayımı için bir salınım modeli eğilimi gösterdi. Sonuç: Genel olarak, toplam biyolojik stabilite, Toplam Mikrobiyal Aerobik Sayım (TAMC) açısından zamanla iyileşir. Biyolojik yük seviyesi ve dalgalanmaların büyüklüğü en son izleme durumuna göre düşmekteydi.

Anahtar Sözcükler: Kutu grafiği, Kontrol Çizelgesi, Belediye Suyu, Poisson Dağılımı, Olasılık Grafiği

Abstract

Background: The microbiological quality of municipal water is an important inspection characteristic that must be carefully monitored and controlled to ensure the delivery of acceptable water that is safe for human activities, consumption and further processing. Case presentation: The current case demonstrated the implementation of a special type of attribute control chart for the examination and analysis of long-term data trends of water distribution in a healthcare facility from different pints-of-use. All datasets showed a right-skewed dispersion pattern of data indicating solitary intermittent high values but without any observable Out-Of-Specification (OOS). All water lines failed to follow any known distribution pattern without the need for transformation which had improved the normality and removed the outliers from datasets. The direct approach for visualizing the record of microbiological results was accomplished using Laney-attribute charts. Discussion: Each use point had its unique trend of data by visualizing the mean, pattern, the Upper Control Limit (UCL) and the alarm types. The net quality of the water distribution system in the facility could be deduced from the overall readings that had been averaged and pooled in a single process-behavior chart. Implementation of this trending chart showed a tendency of oscillation pattern for bioburden count that tended to seize in amplitude with possible signs of seasonality. Conclusion: In general, the overall biological stability is improving with time in terms of the Total Microbial Aerobic Count (TAMC). The Bioburden level and the magnitude of fluctuations were decreasing according to the latest monitoring state.

Keywords: Box plot, Control Chart, Municipal Water, Poisson Distribution, Probability Plot

1. Introduction

The microbiological quality of municipal water is one of the crucial properties that must be controlled to ensure the safety of the water for human activities and consumption (WHO, 2011). The inspection characteristics of water are highly dynamic and can change rapidly from time to time (Chapman, 1996). Thus, regular monitoring must be ensured to take urgent actions when needed (Sciortino and Ravikumar, 2009). The biological stability of the water system is a critical requirement that must be met to ensure compliance of the microbiological water quality with the regulatory authorities around the globe (Prest et al., 2016, https://doi.org/10.3389/ fmicb.2016.00045). It is mandatory to ensure not only an acceptable microbiological water quality that meet the specification limit but also this quality must be stable overtime. Previous studies demonstrated promising short-term work using Individual-Moving Range (I-MR) charts that showed patterns that could aid in the prediction of the microbiological stability of water (Essam Eissa, 2017a). This statistical tool provided an insight into the inspected quality characteristic in chronological order.

Shewhart control charts were originally used in the measuring, monitoring and control of industrial processes since the 1920s (Best, 2006). However, their use could be actually demonstrated in other non-industrial activities and tasks (Essam Eissa, 2017b). Process-behavior charts could provide a good indication for the degree of process improvement or deterioration depending on the pattern of the result changing of the microbial count in successive water samples that are arranged in time order (Şengöz, 2018). A stable trending chart means that a specific measurable process or property might be predicted with time as long as the current measures of control are maintained (Lieberman, 1965). Otherwise, a change in the standard working procedure and/or conditions might influence the trend of the dataset toward either deteriorating or improvement.

The aim of the current case analysis is determined to assess to biological stability of the water distribution system in a selected healthcare facility using quantitative statistical tools, notably the implementation of the Shewhart charts for bioburden trending. The study focused on the microbial bioburden over the long run as one of the critical quality markers of safe water for human activities and consumption using an approach of implementing a sort of attribute-type of the trending diagrams regardless of the underlying spreading pattern of the datasets.

2. Case Description

A municipal water distribution network in a healthcare facility was monitored for a Heterotrophic Plate Count (HPC) over about four years (from 2017 to 2021 except the last quarter of the year 2021) using standard microbial analysis technique and the results were recorded after incubation as Colony Forming Unit per one milliliter (CFU/mL). The plant involved 13 separate use ports for a sampling of the city water distributed through different service partitions. The dataset was saved in the Minitab worksheet and processed using the Statistical Process Control (SPC) tools. All use points of the water samples demonstrated microbial counts that were below the action limit of 100 CFU/mL. Initial examination of data shape and pattern was conducted using a Box Plot diagram (Figure 1). The dispersion of all data showed signs of a positive skew pattern with few outlier values toward the right side (higher microbial count). Screening of the spreading type to identify the distribution of data showed that the current record in its existing state failed to follow specific distributions such as Gaussian or Poisson shape. Attempt to use logarithmic transformation (to the base ten) had minimized the scattering of the groups. Nevertheless, Some points of use did not meet the required distribution assumption for the control chart. In addition, an approach that would facilitate the construction of the trending charts without the need for additional processing steps of conversion then reconversion again to obtain meaningful output would be an advantage that set a priority for itself.

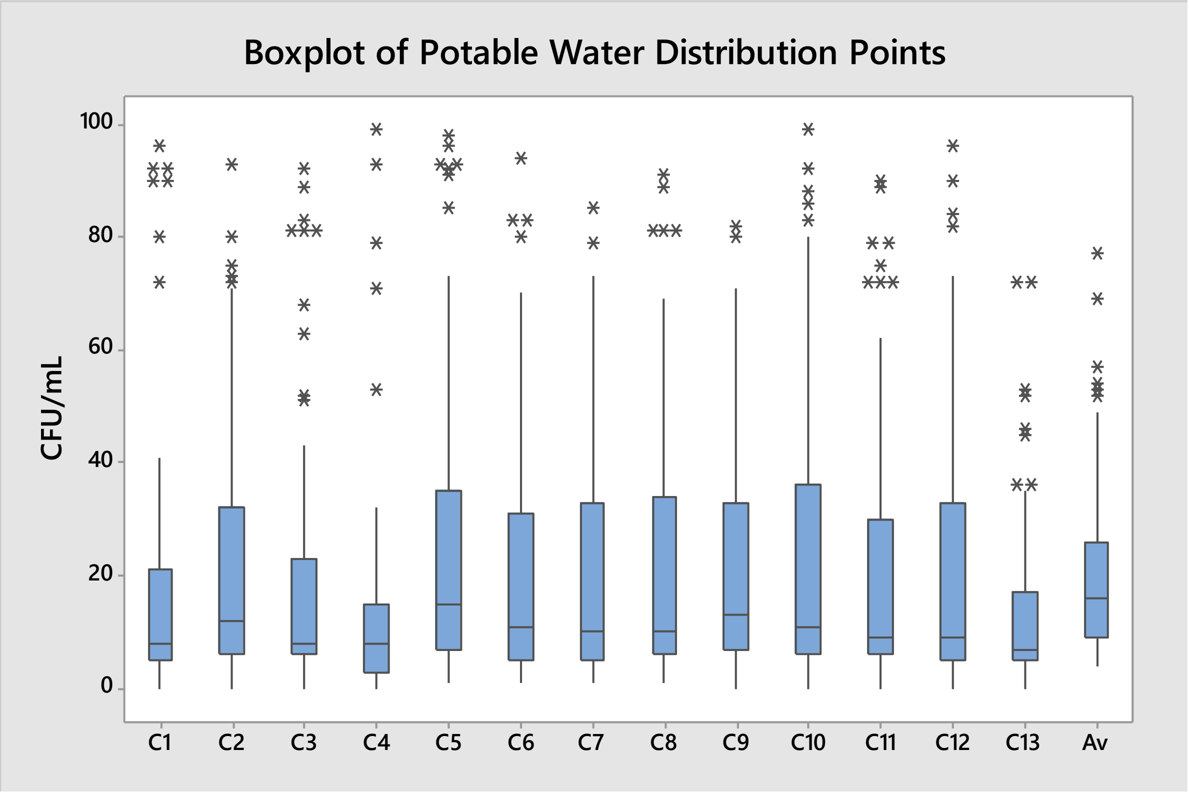
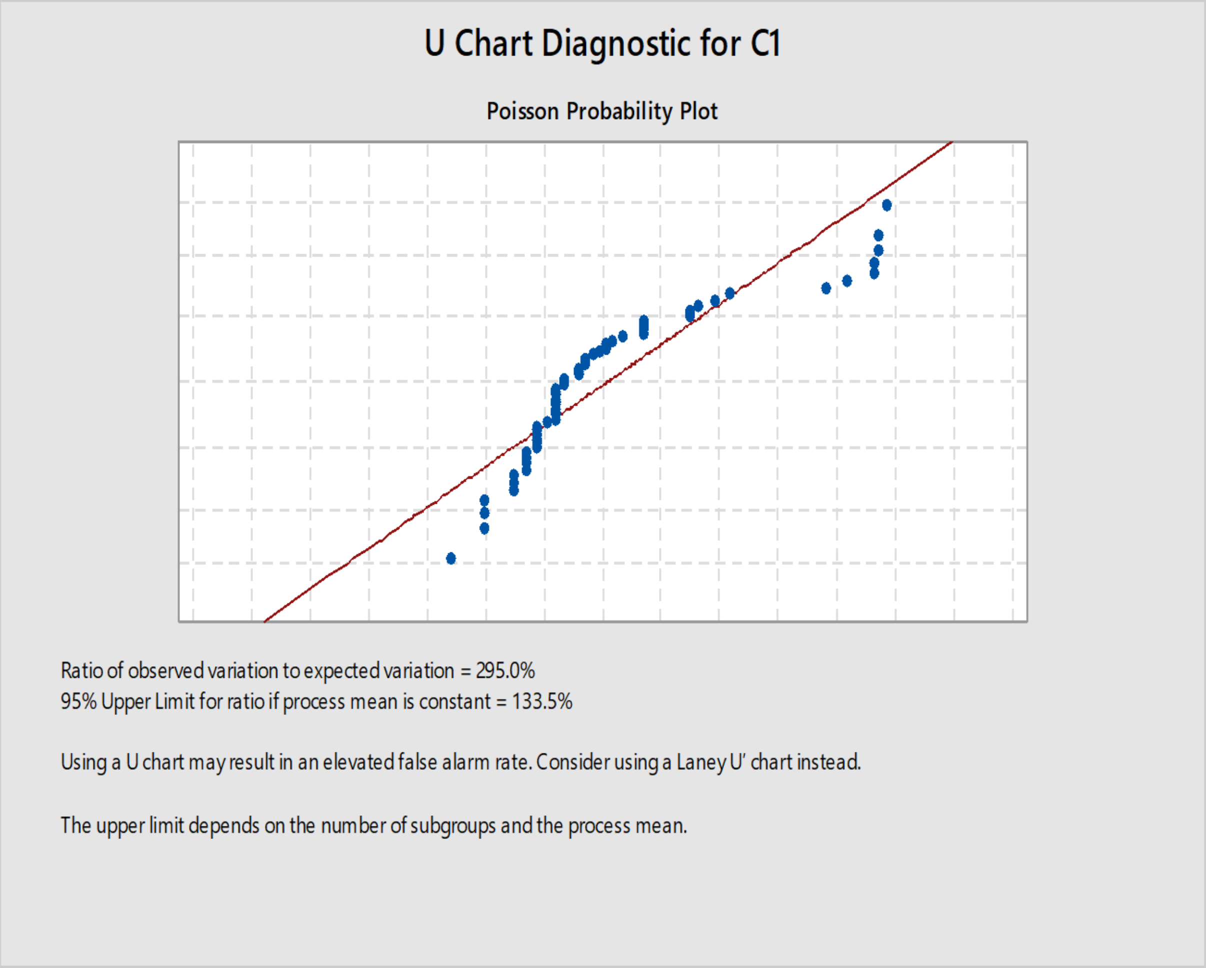


Figure 1: Box plot diagram for microbial count in the point-of-use distribution line for potable water in healthcare facility (asterisks indicates excursion in the results and Av.= Average of all points).

The suitable attribute chart for count data was c or u-type. However, diagnostic examination for fitness showed significant deviation from the assumed distribution (Figures 2–7). Overdispersion existed in all groups suggesting using modifying techniques for correction of the database spreading. The Laney-attribute chart was used as could be seen in Figures 8-14 showing the quantitative measure for the overdispersion Sigma Z (σZ) in each graph for the point-of-use and all were significantly greater than one. The factor of σZ determined using the average of Moving Range (MR) - of length two - divided by the unbiasing constant of 1.128 to correct for dispersion according to its magnitude. Process-behavior charts for each use point showed initial unstable considerable fluctuations in the first year followed by relatively more stable variations that descended in amplitude gradually to some extent. The first section of the charts – with different frequency, magnitude and period - showed intermittent excursions (marked by red points “1”) above 3 Standard Deviations (SD or σ) followed by a new trend embracing shifts in the HPC mean value in the process-behavior charts (indicated by alerting red value “2”). Interestingly, there is a sign of tendency for showing a seasonal variation that could be sensed visually from the control charts graph, especially from the plot of the average microbial quality of the overall water distribution system. Also, impeding cyclic behavior is likely to be viewed on yearly basis in an alternating pattern, except for years 2020 and 2021 as they demonstrated a net of similar trend regardless of the individual use points which illustrated unique fingerprints for each port in the water distribution network for the facility. Nevertheless, the control chart of the overall distribution system showed a minute improvement in the last year with smaller fluctuations than the previous year. Accordingly, two evaluations could be determined, namely, the overall water distribution system and the individual network segments in terms of the total microbiological count (CFU) per one (mL) of the sample for long-term inspection of the low-frequency sampling process.



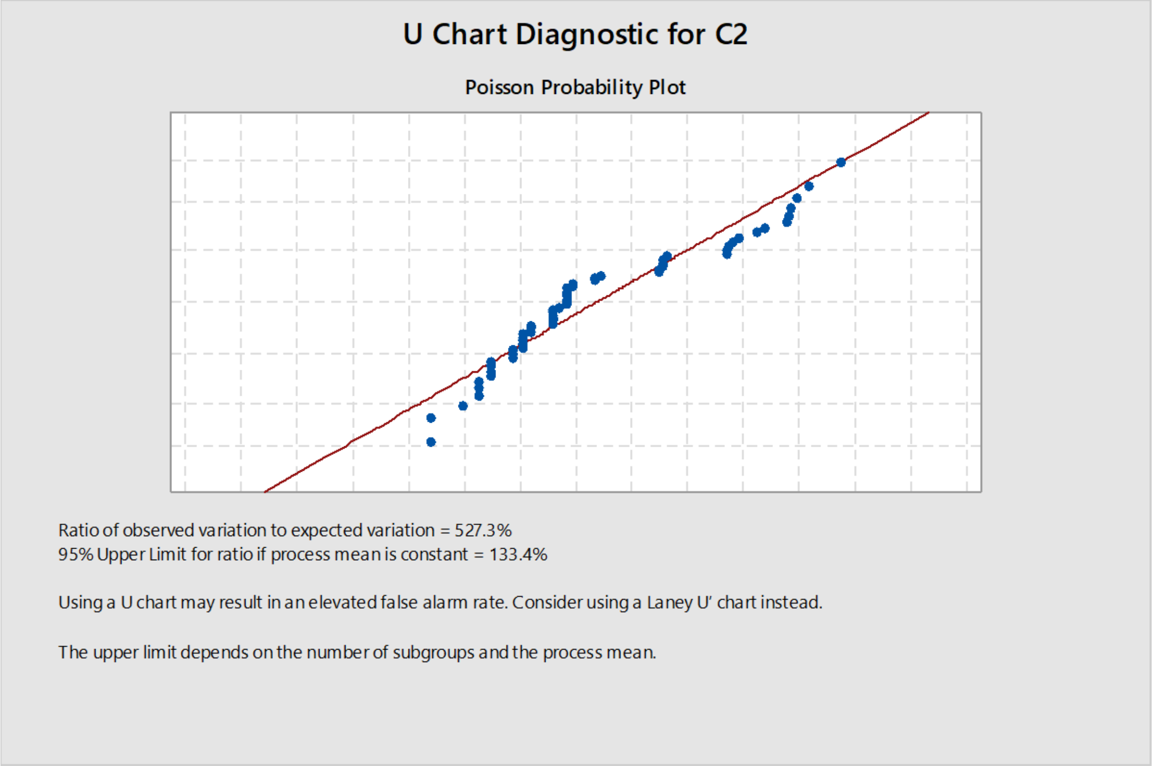
U Chart Diagnostic for C1

Poisson Probability Plot

Ratio of observed variation to expected variation = 295.0%
95% Upper Limit for ratio if process mean is constant = 133.5%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U′ chart instead.

The upper limit depends on the number of subgroups and the process mean.

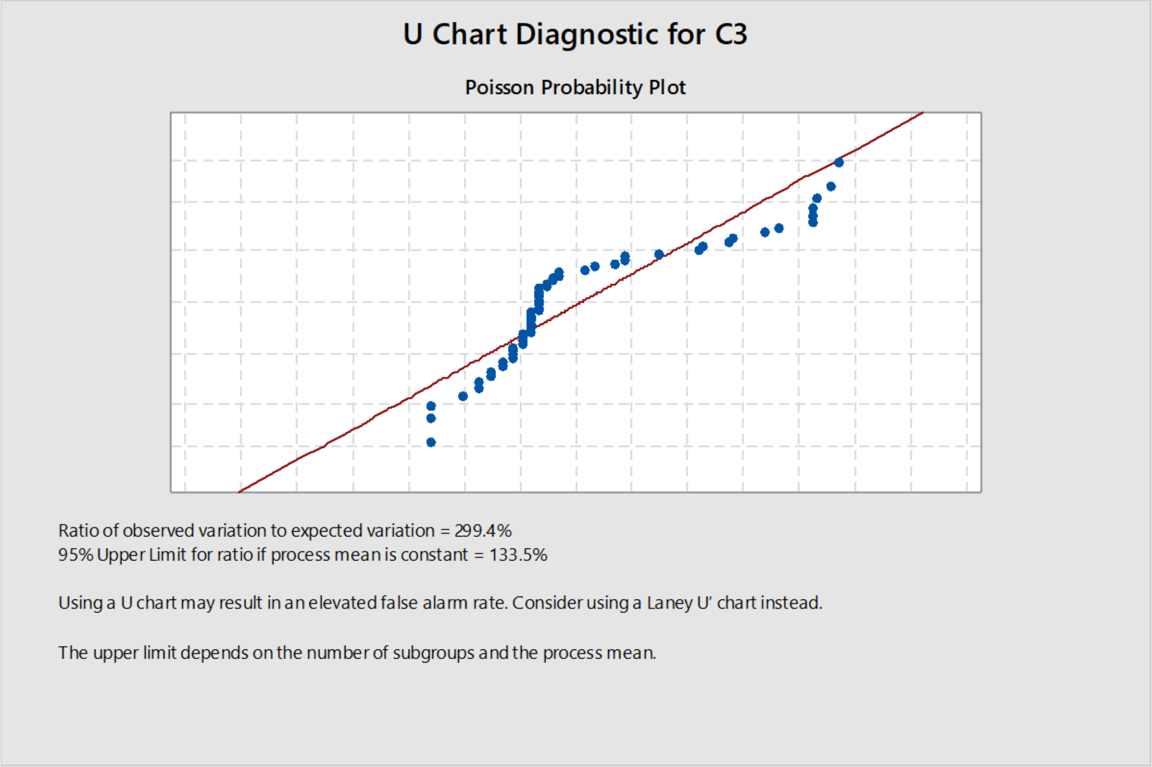


Ratio of observed variation to expected variation = 527.3%
95% Upper Limit for ratio if process mean is constant = 133.4%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U′ chart instead.

The upper limit depends on the number of subgroups and the process mean.

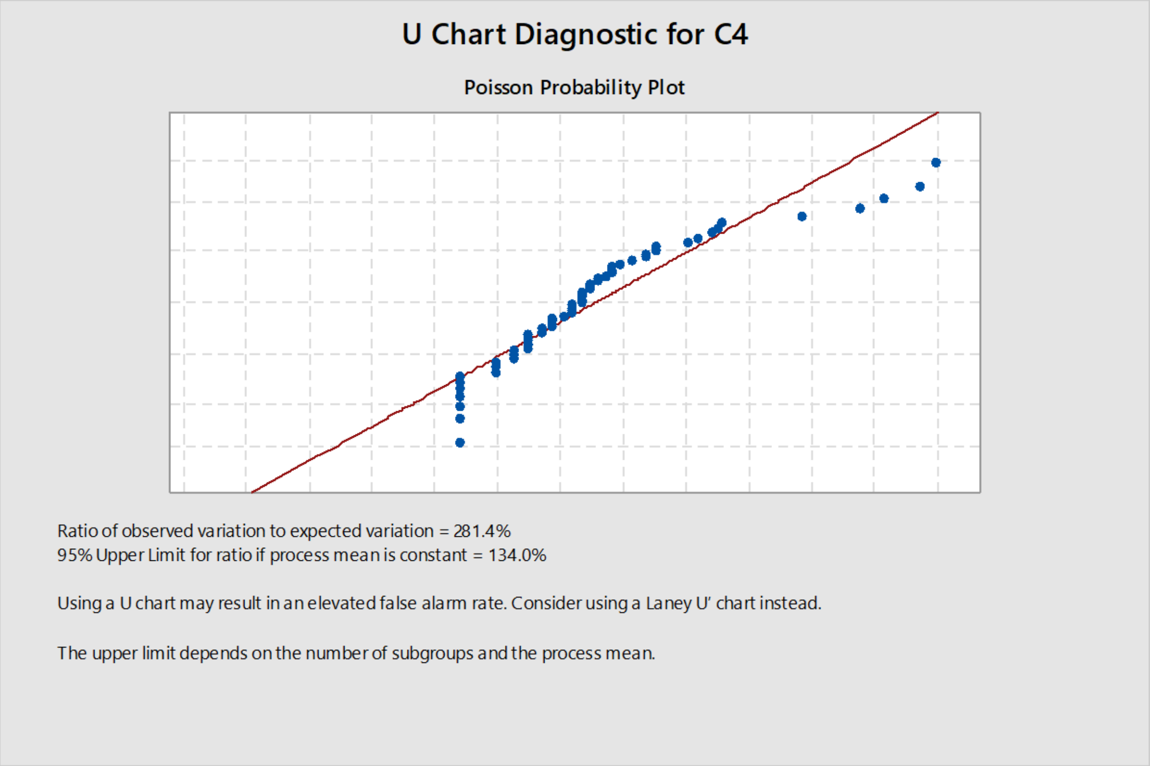
Figure 2: Data fitness analysis for Poisson distribution for the use ports C1 and C2.



Ratio of observed variation to expected variation = 299.4%
95% Upper Limit for ratio if process mean is constant = 133.5%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U′ chart instead.

The upper limit depends on the number of subgroups and the process mean.

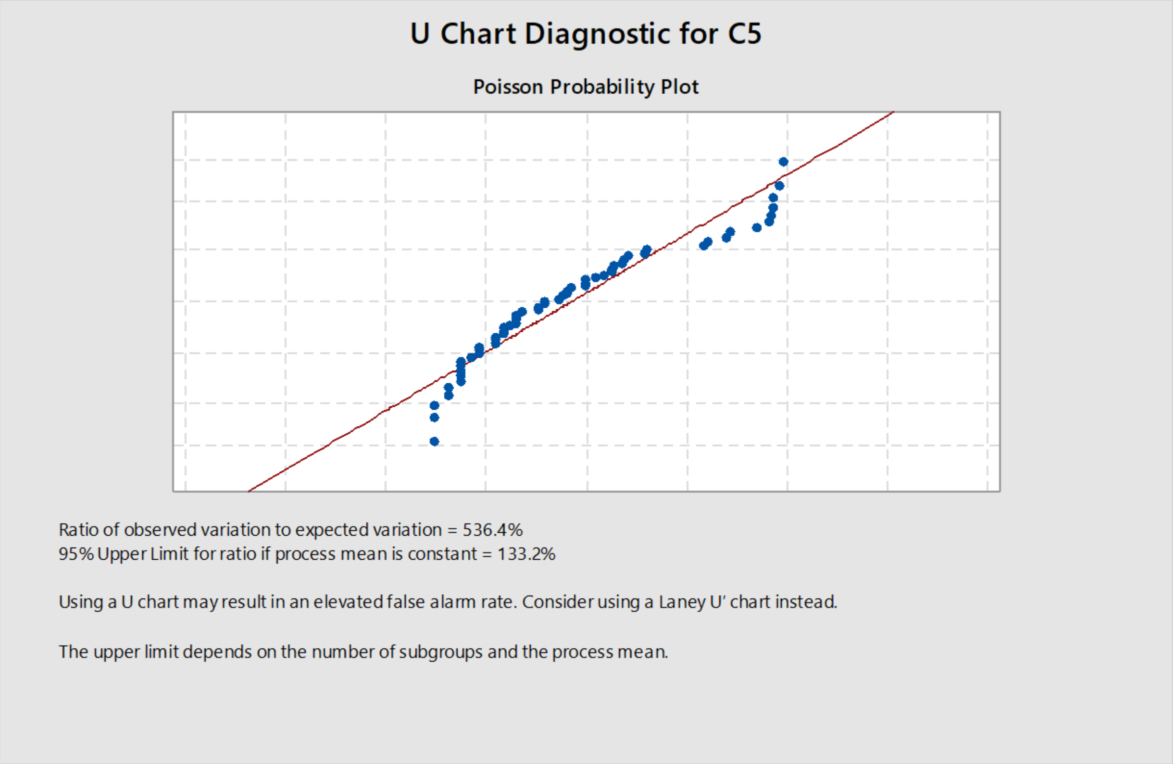


Ratio of observed variation to expected variation = 281.4%
95% Upper Limit for ratio if process mean is constant = 134.0%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.

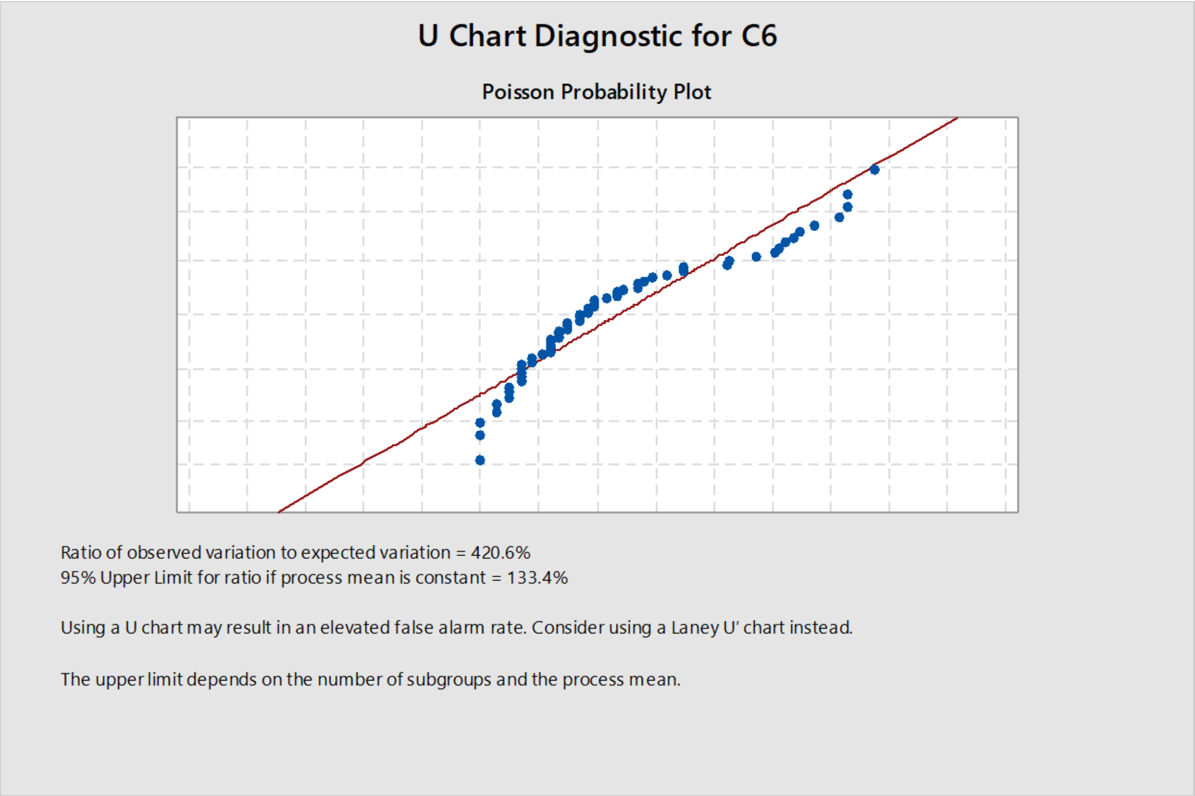
Figure 3: Data fitness analysis for Poisson distribution for the use ports C3 and C4.



Ratio of observed variation to expected variation = 536.4%
95% Upper Limit for ratio if process mean is constant = 133.2%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.

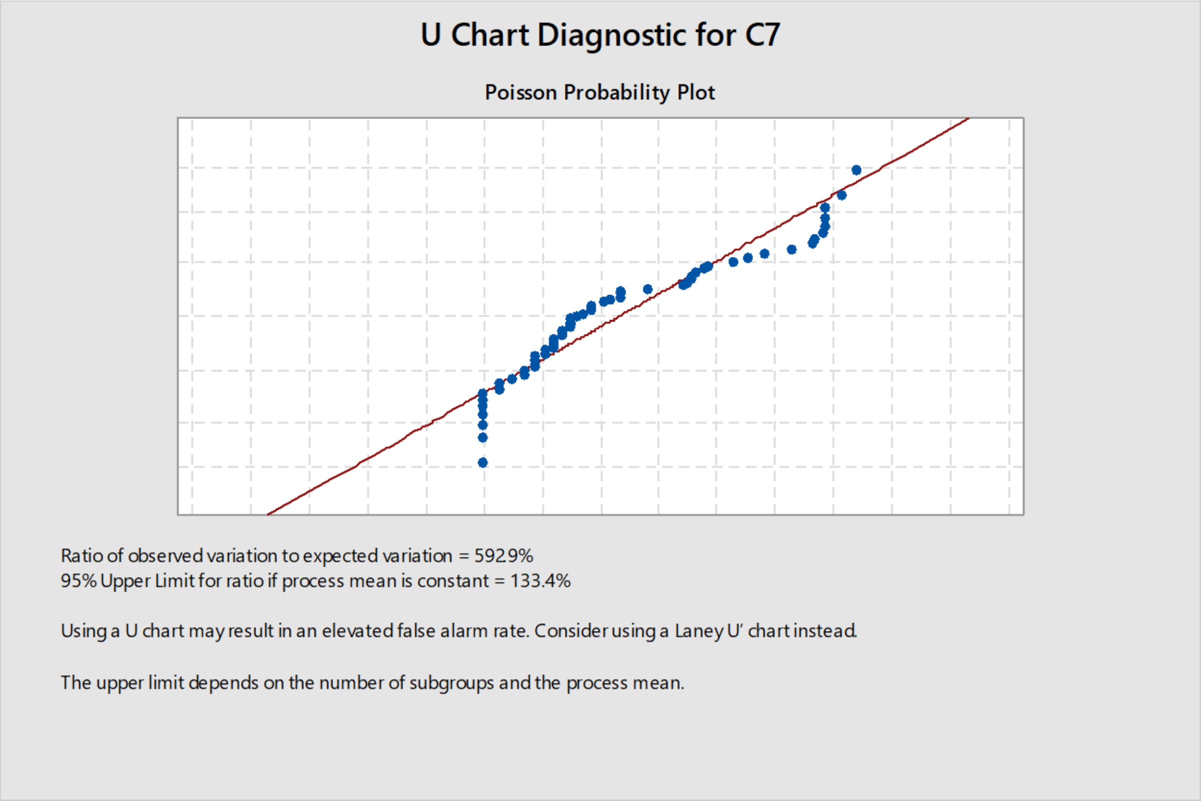


Ratio of observed variation to expected variation = 420.6%
95% Upper Limit for ratio if process mean is constant = 133.4%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U′ chart instead.

The upper limit depends on the number of subgroups and the process mean.

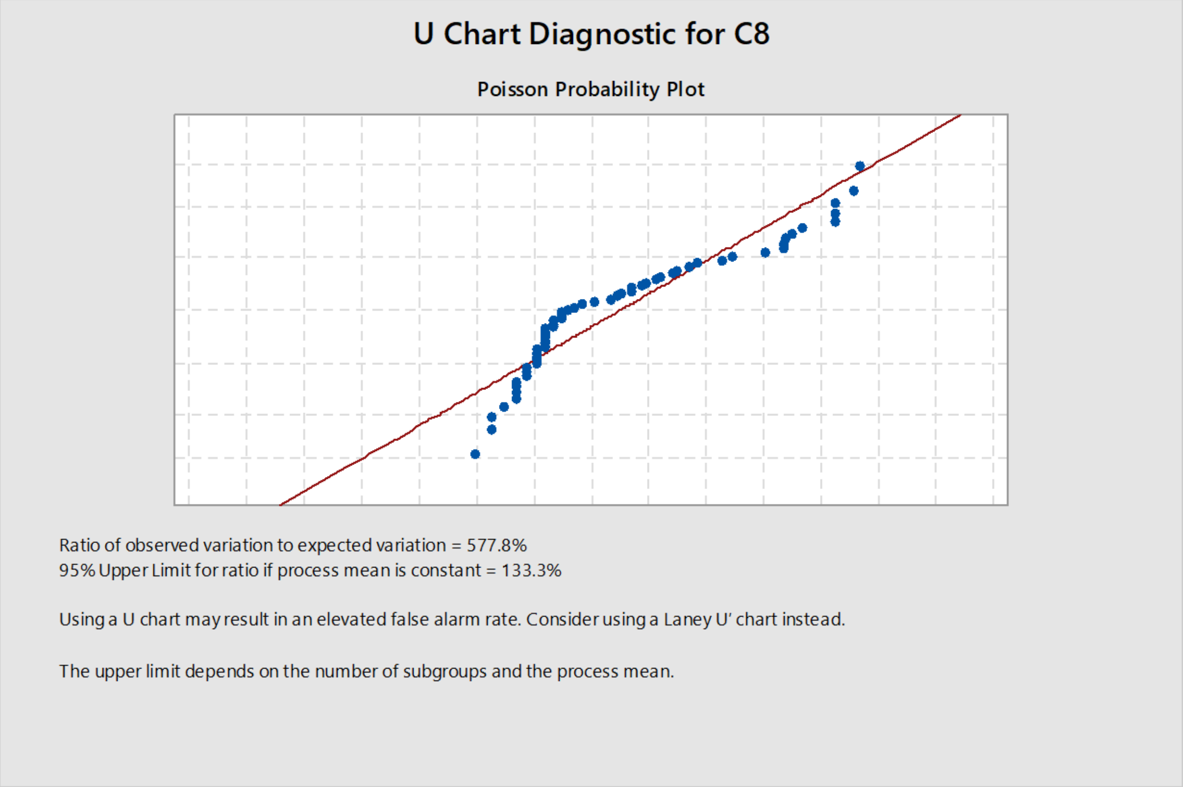
Figure 4: Data fitness analysis for Poisson distribution for the use ports C5 and C6.



Ratio of observed variation to expected variation = 592.9%
95% Upper Limit for ratio if process mean is constant = 133.4%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U′ chart instead.

The upper limit depends on the number of subgroups and the process mean.


U Chart Diagnostic for C8

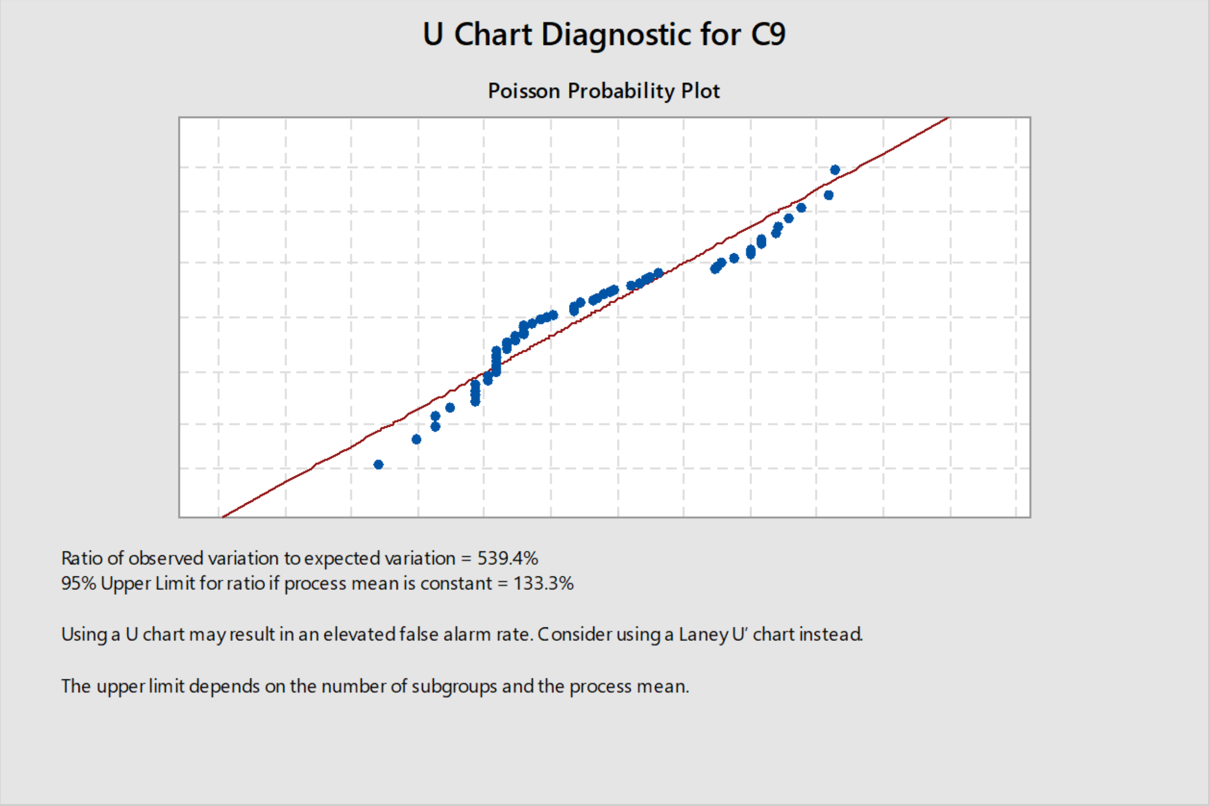
Poisson Probability Plot

Ratio of observed variation to expected variation = 577.8%
95% Upper Limit for ratio if process mean is constant = 133.3%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.

Figure 5: Data fitness analysis for Poisson distribution for the use ports C7 and C8.

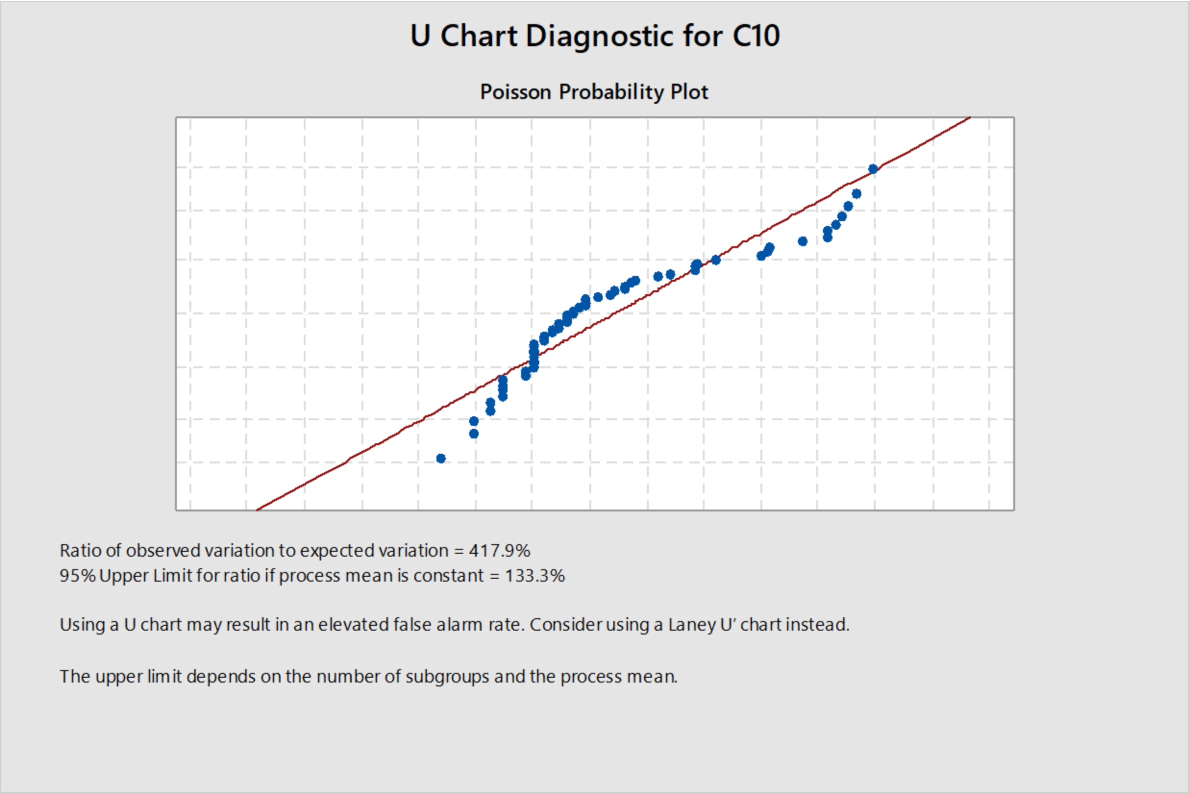

U Chart Diagnostic for C9

Poisson Probability Plot

Ratio of observed variation to expected variation = 539.4%
95% Upper Limit for ratio if process mean is constant = 133.3%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.

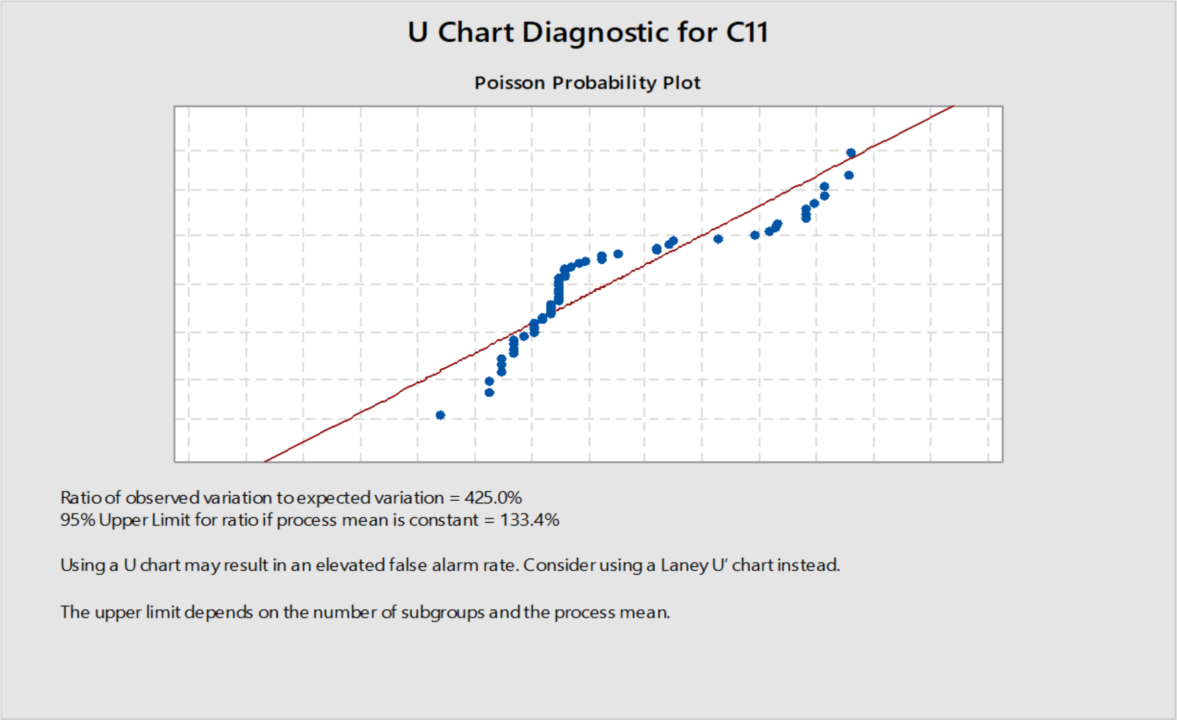


Ratio of observed variation to expected variation = 417.9%
95% Upper Limit for ratio if process mean is constant = 133.3%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.

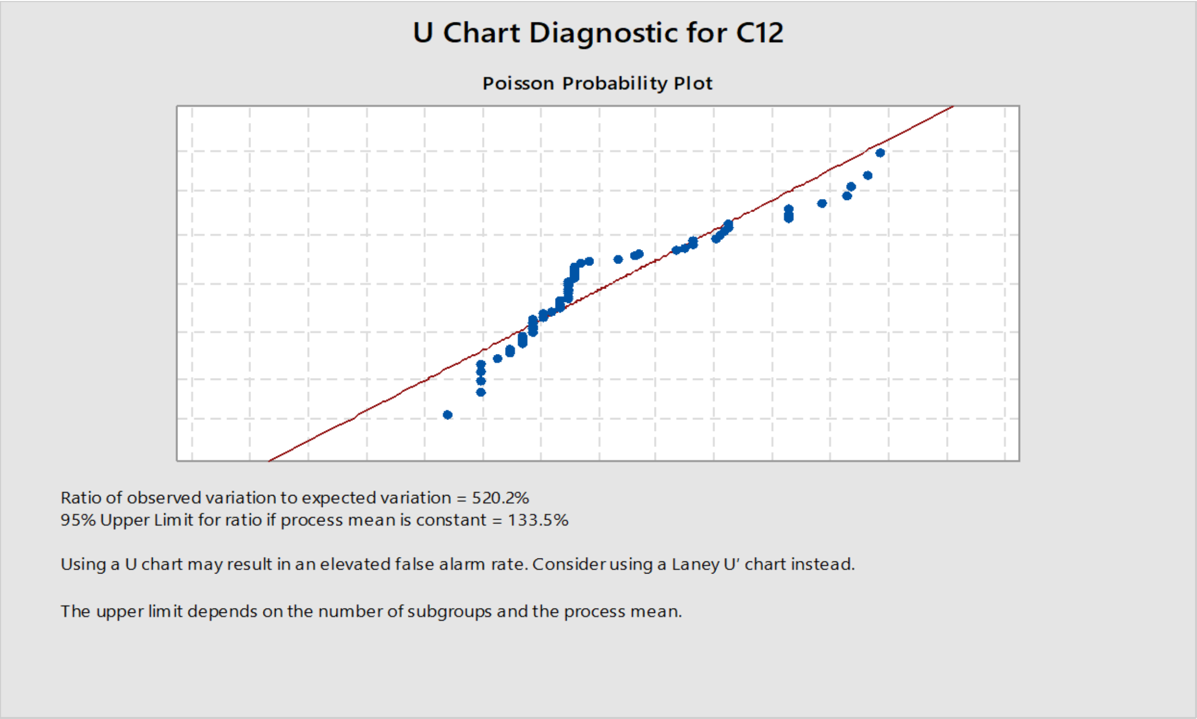
Figure 6: Data fitness analysis for Poisson distribution for the use ports C9 and C10.



Ratio of observed variation to expected variation = 425.0%
95% Upper Limit for ratio if process mean is constant = 133.4%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

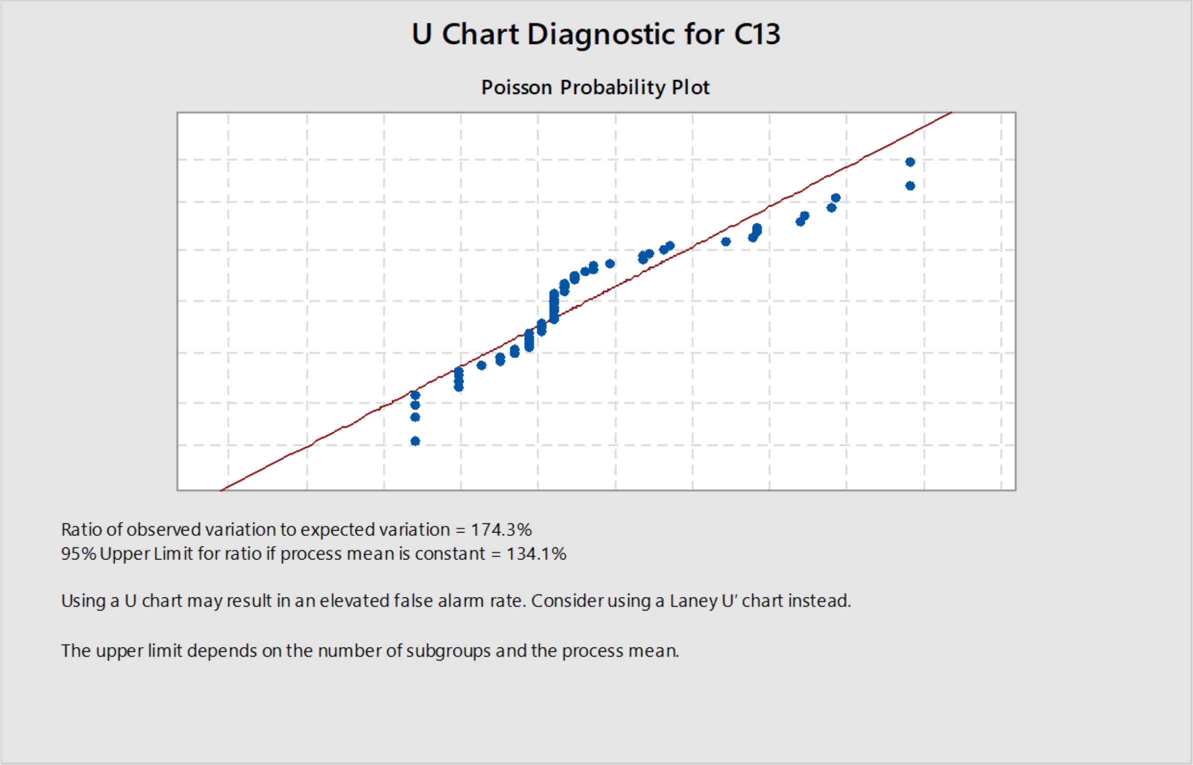
The upper limit depends on the number of subgroups and the process mean.



Ratio of observed variation to expected variation = 520.2%
95% Upper Limit for ratio if process mean is constant = 133.5%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.



Ratio of observed variation to expected variation = 174.3%
95% Upper Limit for ratio if process mean is constant = 134.1%

Using a U chart may result in an elevated false alarm rate. Consider using a Laney U' chart instead.

The upper limit depends on the number of subgroups and the process mean.

Figure 7: Data fitness analysis for Poisson distribution for the use ports C11, C12 and C13.

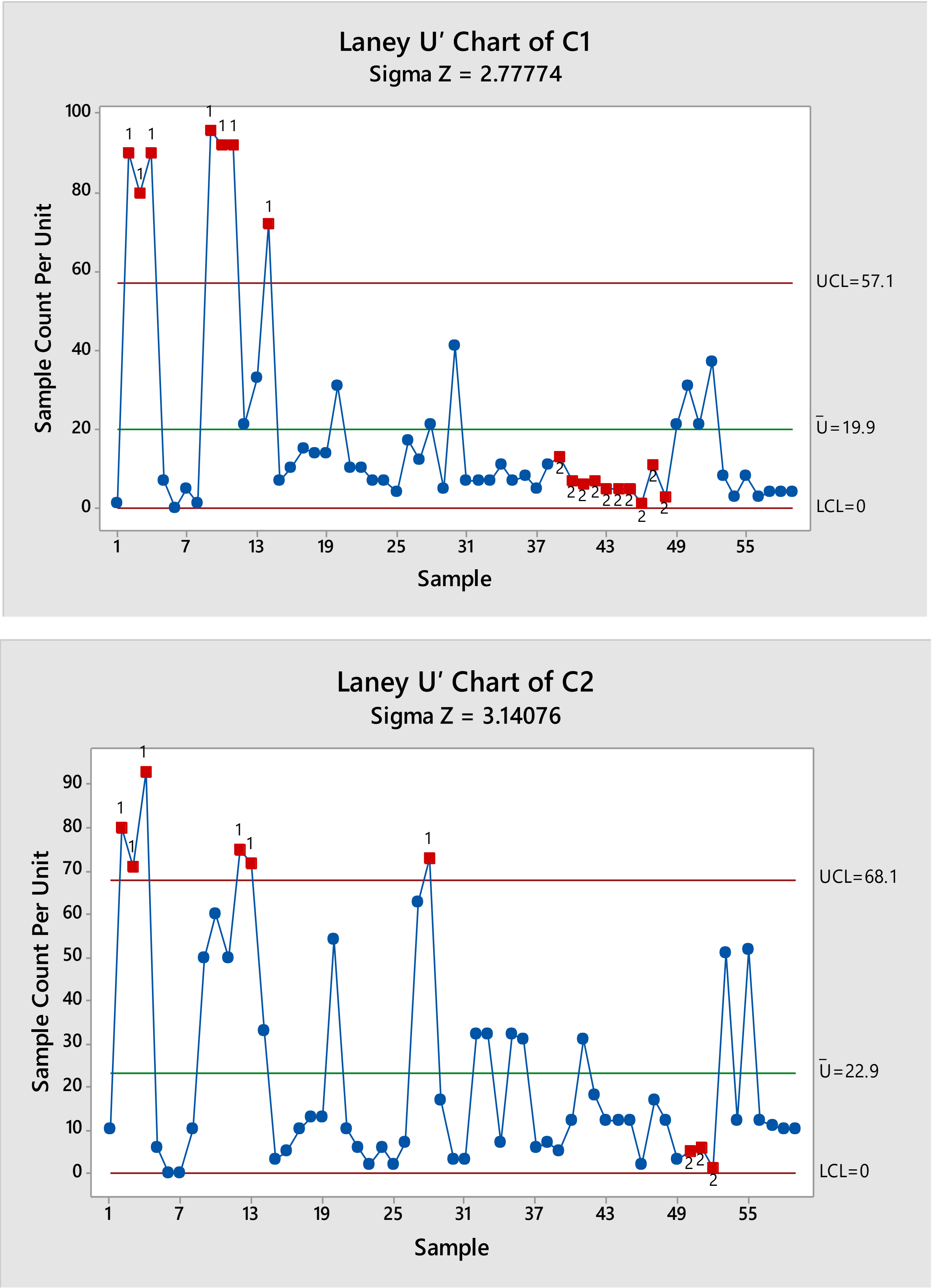
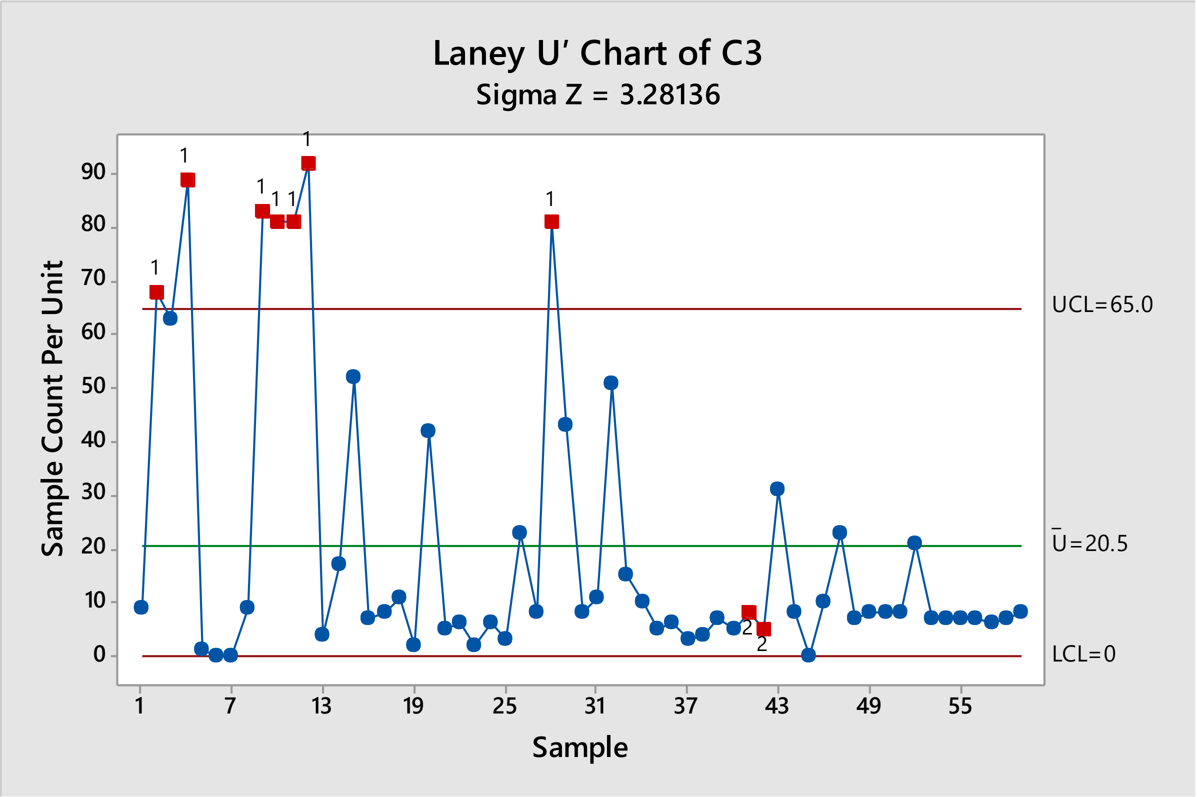


Figure 8: Laney trending profile for distribution points C1 and C2. (Red dots are out-of-control reading values)



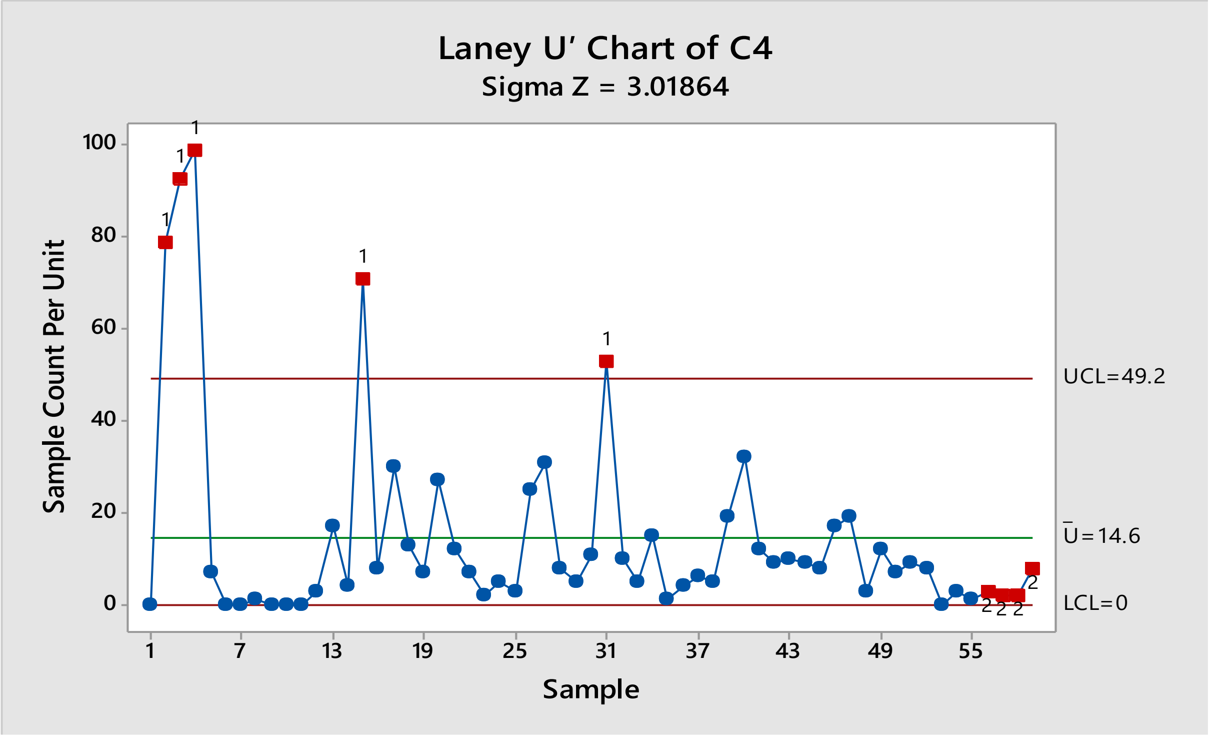


Figure 9: Laney trending profile for distribution points C3 and C4. (Red dots are out-of-control reading values)

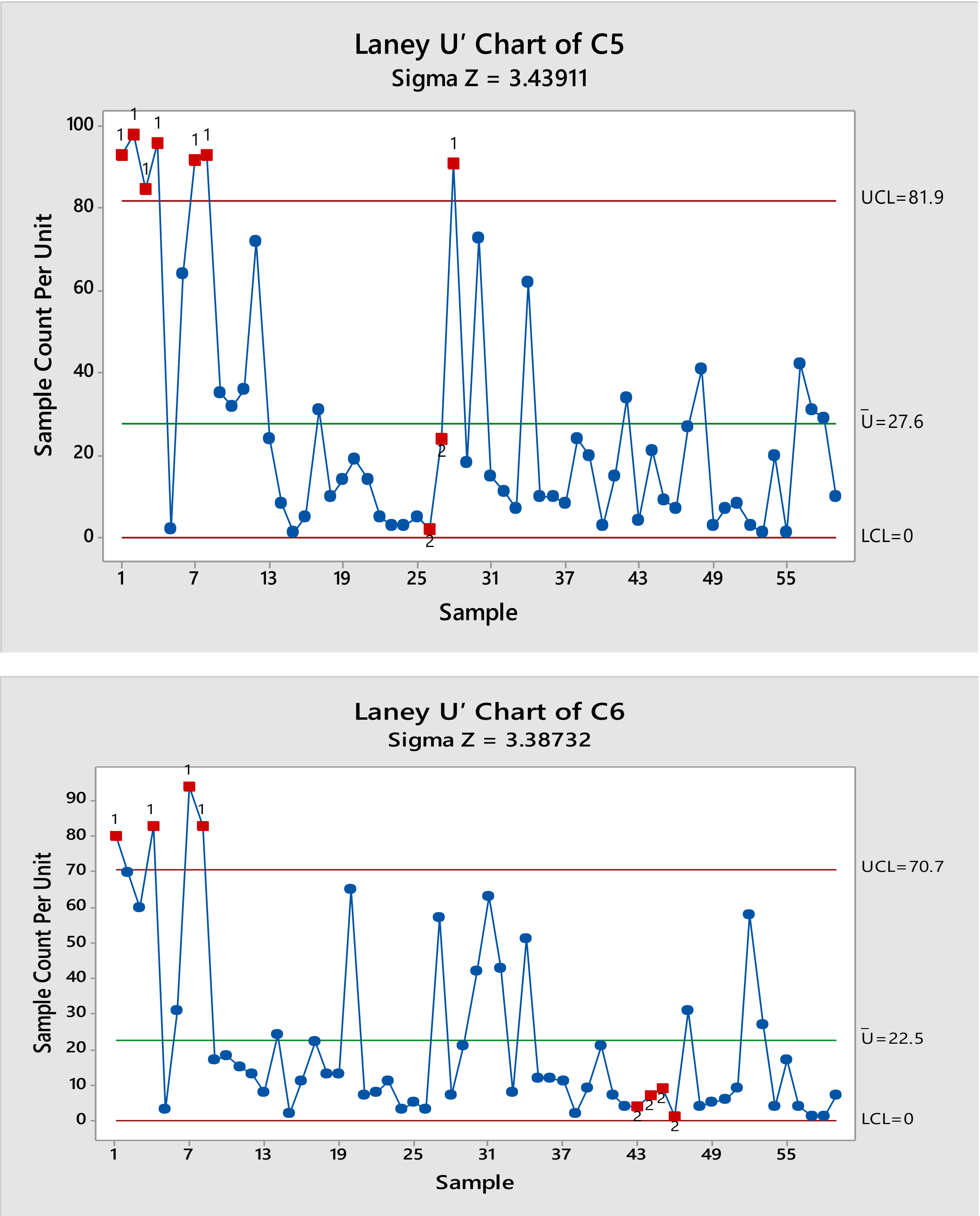
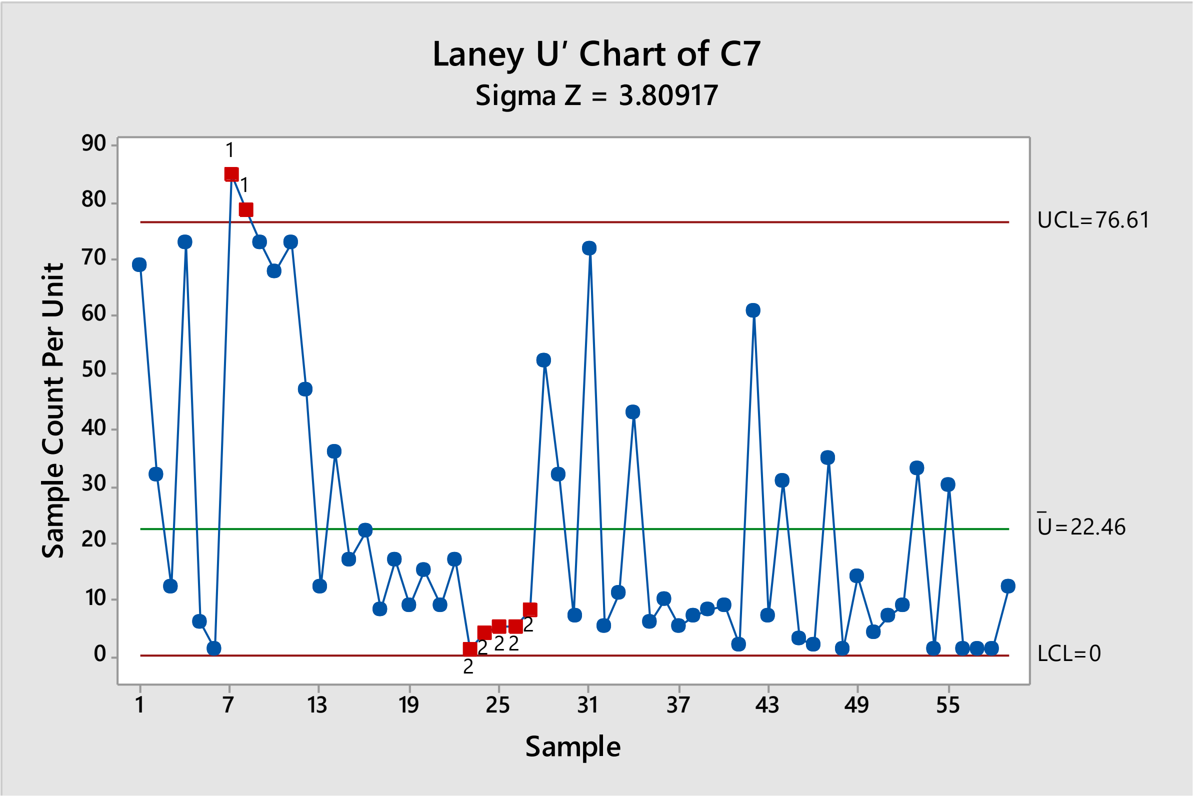


Figure 10: Laney trending profile for distribution points C5 and C6. (Red dots are out-of-control reading values)



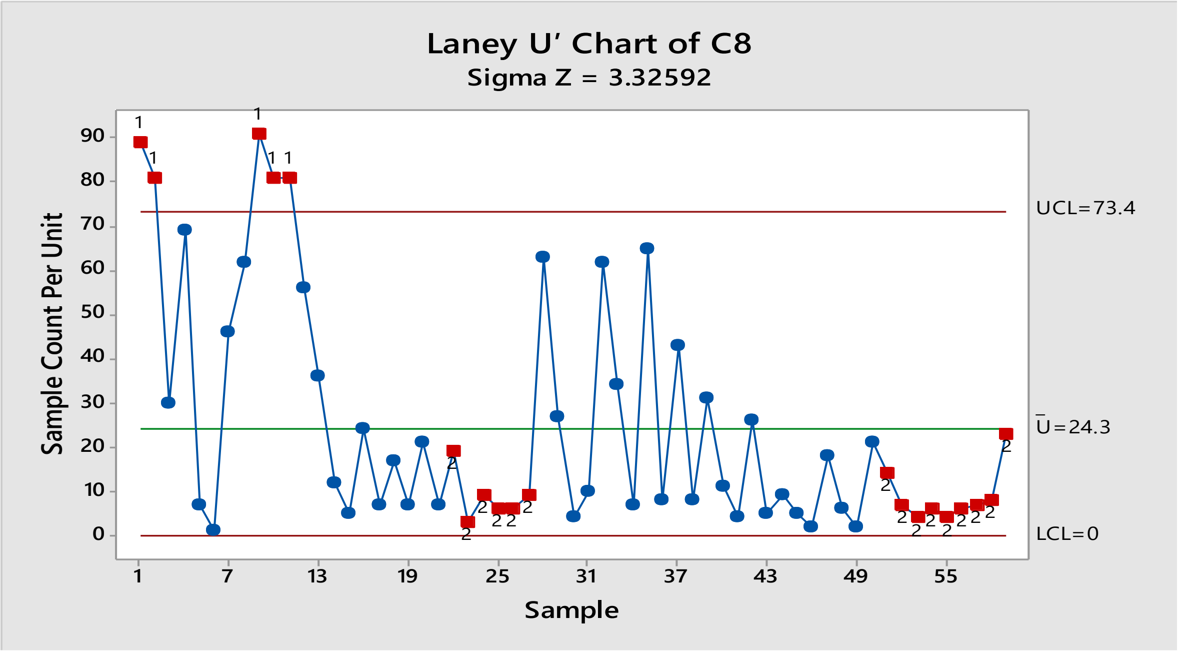


Figure 11: Laney trending profile for distribution points C7 and C8. (Red dots are out-of-control reading values)

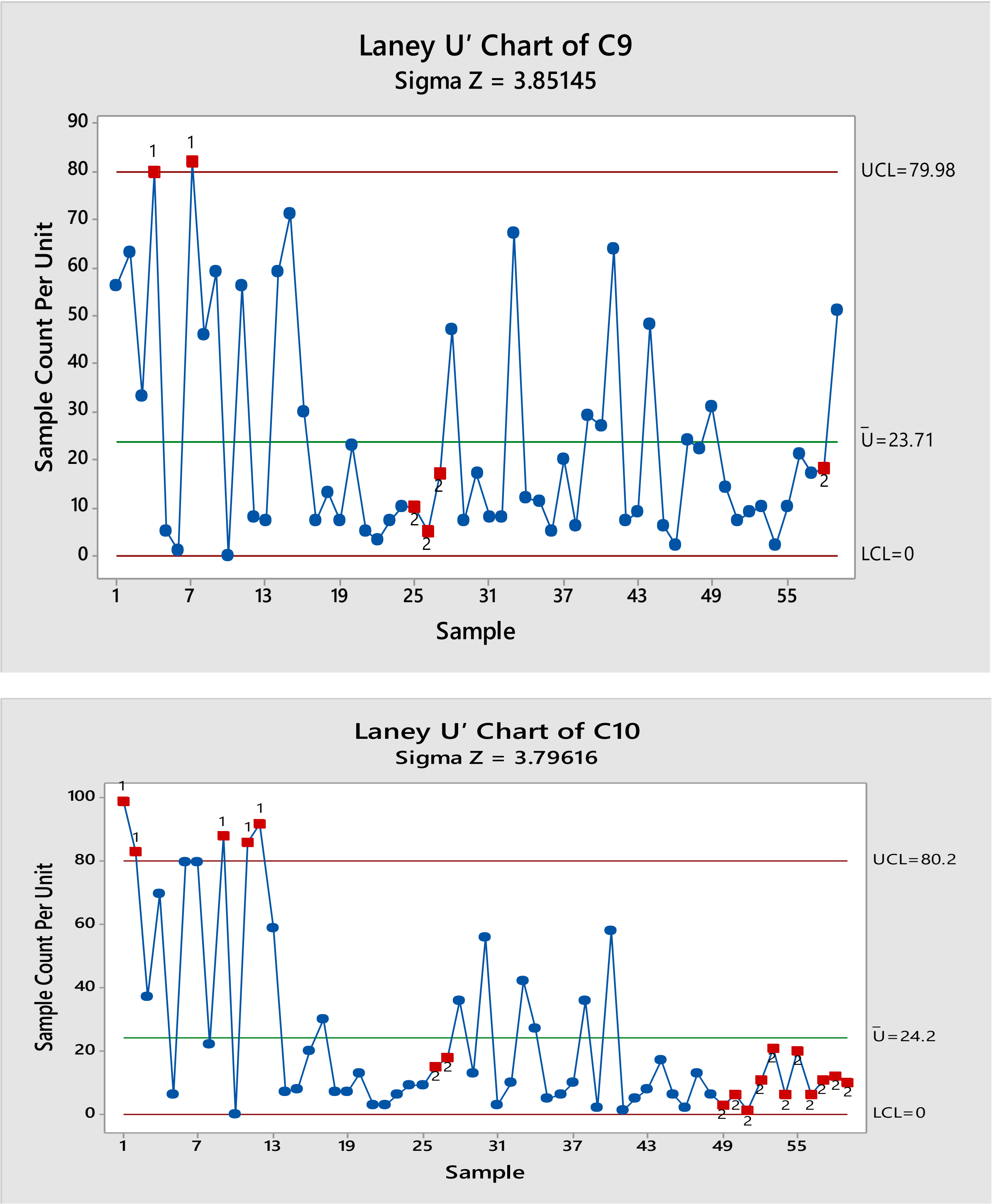


Figure 12: Laney trending profile for distribution points C9 and C10. (Red dots are out-of-control reading values)

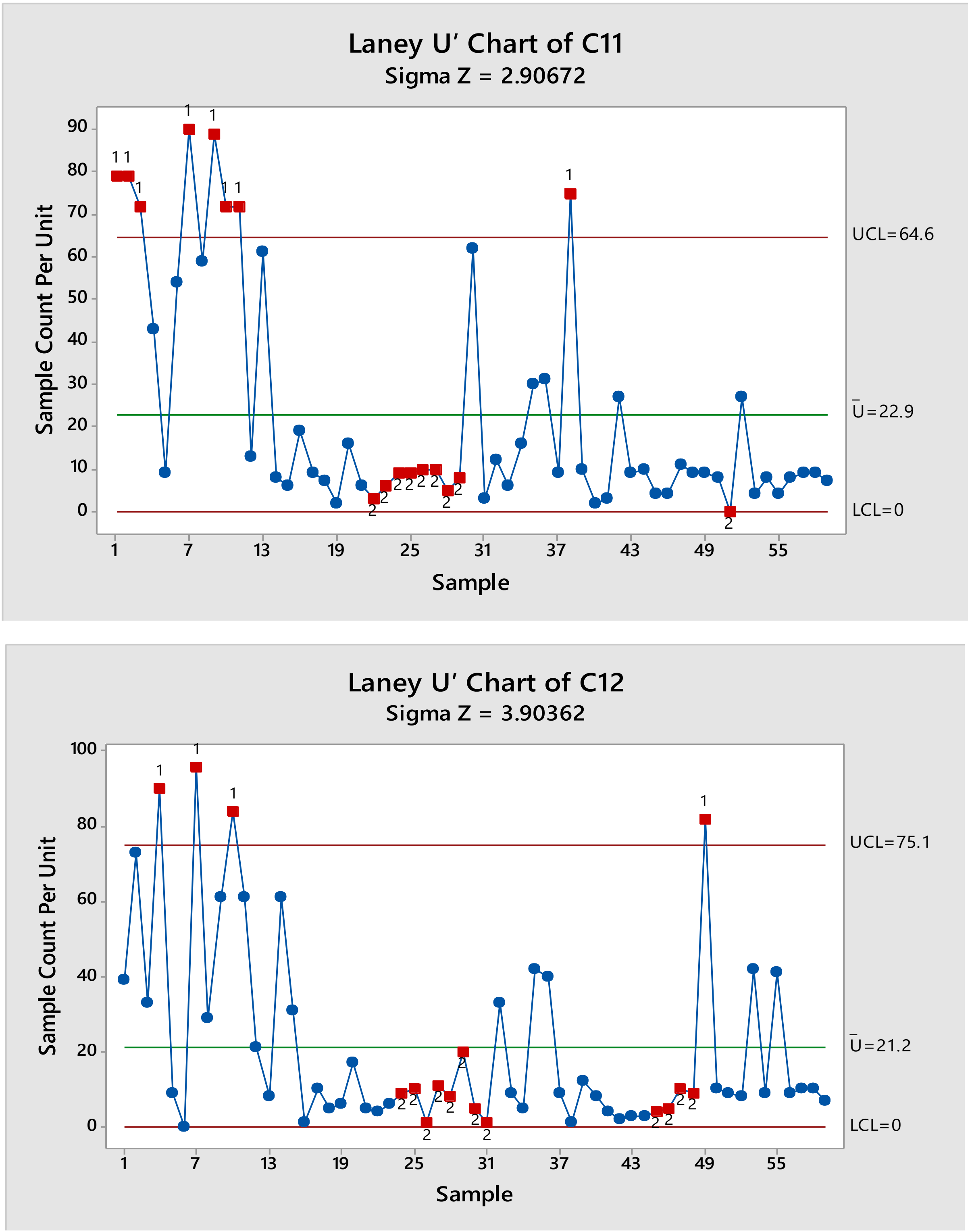
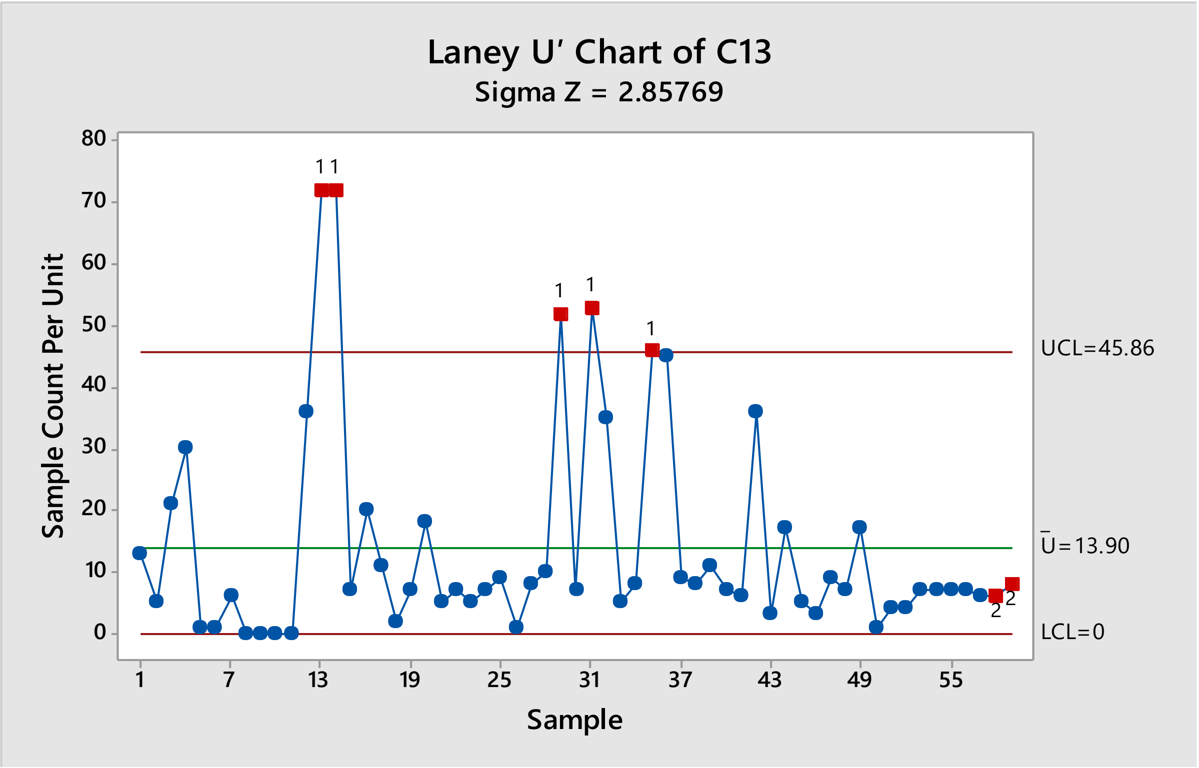


Figure 13: Laney trending profile for distribution points C11 and C12. (Red dots are out-of-control reading values)



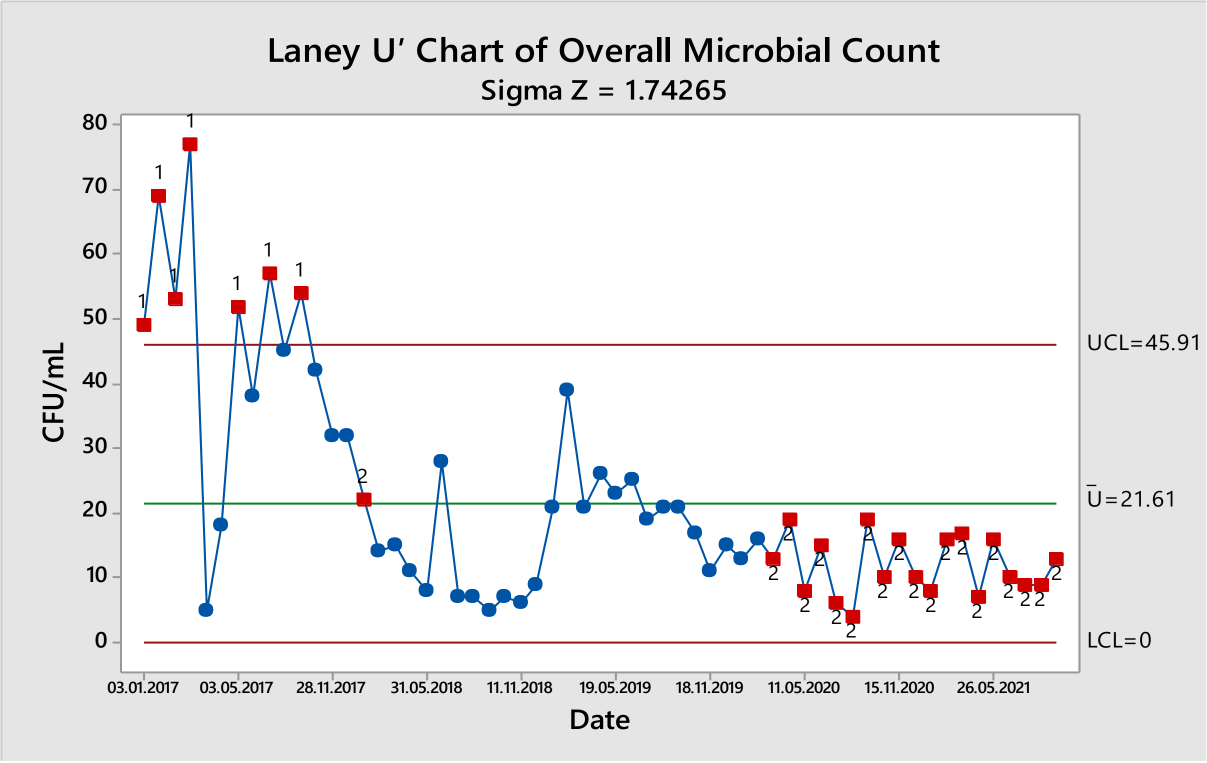


Figure 14: Laney trending profile for distribution points C13 and the overall water line quality. (Red dots are out-of-control reading values)

3. Discussion

Examination of the distribution of the microbial count (expressed as CFU/mL) from long-term monitoring of municipal distribution network in the healthcare facility showed a non-normal pattern of spreading for the dataset (Bordner et al., 1978). Each group showed significant skew to the right side of the distribution as could be seen in Figure 1 using a box plot diagram. This is normally would be expected as the major trend of microbiological count tended to concentrate in the direction of the lower bioburden (Bordner et al., 1978). Notably, the presence of aberrant values (indicated by asterisks in the graph) influenced the direction of each point-of-use record. This is due to the presence of a sporadic high microbial count in some samples relative to the general trend for each port (Ashutosh et al., 2018). In the same line, there is not enough evidence in hand to justify omitting these excursions in the results from the data record. Distribution type obviously would impact the selection and the outcome of the process-behavior chart (Khan, 2013). False alarming point frequency and control limits might be affected if the underlying data spreading did not fit the hypothesized distribution required from the trending chart.

While C or U-type control charts were found to be convenient for trending bioburden data in water and pharmaceutical products, yet the current database showed the distribution of the groups that deviate from Poisson patterns for all point-of-use (Figures 2-7) (Eissa et al., 2021). Moreover, the distribution identification study did not reveal any significant compliance with the required assumed distributions needed for the construction of the Shewhart plots. The best approach was saught from the previous experience – other than data transformation (e.g. logarithmic, square, Box-Cox and Johnson transformations among other techniques) - to use Laney modification method for correction of data spreading (Muhammed and Laney, 2006). Alternatively, $\bar{x}$-MR charts have been reported previously to yield a similar outcome with Laney graphs. Nevertheless, Laney trending Figures (8-14) revealed useful and convenient results that could be used for important and useful conclusions concerning the microbiological stability and quality of city water in terms of the total aerobic microbial count (TAMC).

In the current study, Control charts showed important four information. First, a trend of data over time would reveal the chronological pattern and behavior of microbial count data (Ramirez, 2012). The second point is the average of all records for each use point, in addition to the average for the whole facility (the last graph in Figure 14) (Allen, 2019). The third measurable value was the Upper Control Limits (UCLs). This criterion would be affected by data dispersion and not only the mean (Khan, 2013). Lower Control Limits (LCLs) were not of great concern in the present case as the microbiological count result relies on a one-sided analysis criterion, that is CFU/mL (Eissa, 2019). UCL marked the boundary of the assessed inspection characteristics beyond which any microbial count would be considered an outlier value (alarm point "1"). Control Limits (CLs) windows could be considered as a measuring marker of the process stringency and stability (Noskievičová, 2013). Thus, a tighter trend would have a narrow range where fluctuations are minimum. The fourth examination property in the trending charts is alarming (aberrant) readings detection and spotting.

Out-Of-Control (OOC) points in the control charts were marked as red points. Test for assignable-cause identification was important to detect and isolate special-cause from the common-cause variations in the Shewhart charts (Moore and Murphy, 2013). Each point had a number that indicated the type of excursion. Among four-alarm types in this attribute control chart, two distinct OOC were evident in all charts viz. "1" and "2". The first alarm showed freak spiking of HPC above three standard deviations i.e. above the UCL but not necessarily Out-Of-Specification (OOS) as in the current studied case (Noskievičová, 2013). On the other hand, the second alarm is not out of the CL window. However, it demonstrated the persistent presence of at least nine points (plate count readings) on one side of the centerline (Adam et al., 1992). This alarm could be used as an indication of the drift in the process mean which might be a sign for either improvement or deterioration of the inspection property depending on the direction of the shift in the HPC value with the elapsed time.

The sampling port "C13" showed beneficially the lowest average microbial count (14 CFU/mL) with the lowest variance of 293 (SD ≈ 17) in the examined focus group of the plant. In contrast, the point-of-use "C5" demonstrated the highest mean HPC of 28 CFU/mL with a variance value of about 875 (SD ≈ 30). This observation could be visualized and concluded clearly in the trending charts for each use point by recording the means and the UCLs. The present work is limited by addressing microbial count and detection of the common objectionable microorganisms~~;~~ in water. However, it does not address the analysis of the bioburden diversity or effect of the time-in-day which should be investigated thoroughly in another separate study (Adani et al., 2001; Wu et al. 2012). However, the current report provided enough evidence for the promising validity of the quantitative estimation of the biological stability from the perspective of SPC techniques that embraced process-behavior charts as they pinpointed the direction towards improvement and stabilization. Moreover, a similar methodology might be adopted for the city water system provided that the suitable technology would be available for in-deep study (e.g. on-time detection and enumeration of all or most aquatic microbial population) of the water samples in a continuous program to generate sufficient trends to derive a comprehensive and meaningful conclusion.

4. Conclusion and Suggestions

The described case herein showed the indispensable and useful application of Laney-corrected attribute control chart in the analysis of the biological stability of municipal water. The overall performance showed gradual improvement over about four years. However, the overall pattern showed signs of periodical fluctuation, although it was impeding with time. It is worth noting that the last year 2021 showed significant improvement in water quality by a stable fluctuation and reduction in the microbial count and the emergence of a new trend. The implemented technique of SPC could found an important, fast yet simple application in water quality monitoring and control in the pharmaceutical and other healthcare fields which is critical to deliver safe consumable water, especially in the world of an ever-growing population of health and immune-deficient patients. Further extension of this study would be of great interest using other statistical tools such as Principal Component Analysis (PCA) that could cover also other quality characteristics of water such as Total Organic Carbon (TOC) and conductivity tests.

References

Adams, B., Woodall, W., and Lowry, C. (1992). The Use (and Misuse) of False Alarm Probabilities in Control Chart Design. *Frontiers In Statistical Quality Control 4*, 4, 155-168. https://doi.org/10.1007/978-3-662-11789-7_11

Adani, F., Lozzi, P., and Genevini, P. (2001). Determination of Biological Stability by Oxygen Uptake on Municipal Solid Waste and Derived Products. *Compost Science &Amp;* Utilization, *9*(2), 163-178. https://doi.org/10.1080/1065657x.2001.10702031

Allen, T. (2019). *Introduction to Engineering Statistics and Lean Six Sigma*. London: Springer.

Ashutosh, K., Ashutosh, M., and Gandotra, A. (2018). Wastewater quality assessment and its improvement using cost effective methodologies for reuse in livestock. *Indian Journal Of Animal Nutrition*, *35*(3), 313. https://doi.org/10.5958/2231-6744.2018.00047.6

Best, M. (2006). Walter A Shewhart, 1924, and the Hawthorne factory. *Quality and Safety In Health Care*, *15*(2), 142-143. https://doi.org/10.1136/qshc.2006.018093

Bordner, R., Winter, J., and Scarpino, P. (1978). *Microbiological methods for monitoring the environment*. Springfield: Environmental Protection Agency, Office of Research and Development, Environmental Monitoring and Support Laboratory.

Eissa, M. (2019). Extended application of statistical process control-quantitative risk assessment techniques to monitor surgical site infection rates. *International Medicine*, *1*(4), 225-230. https://doi.org/10.5455/im.47174

EİSSA, M., Rashed, E., and Eissa, D. (2021). Implementation of Modified Q-Control Chart in Monitoring of Inspection Characteristics with Finite Quantification Sensitivity Limits: A Case Study of Bioburden Enumeration in Capsule Shell. *El-Cezeri Fen Ve Mühendislik Dergisi*, *8*(3), 1093-1107. https://doi.org/10.31202/ecjse.871179

Essam Eissa, M. (2017a). Determination of the Microbiological Quality of Feed City Water to Pharmaceutical Facility: Distribution Study and Statistical Analysis. *ATHENS JOURNAL OF SCIENCES*, *4*(2), 143-160. https://doi.org/10.30958/ajs.4-2-4

Essam Eissa, M. (2017b). Monitoring of Cryptosporidium spp. Outbreaks Using Statistical Process Control Tools and Quantitative Risk Analysis Based on NORS Long-term Trending. *Microbiology Journal*, *9*(1), 1-7. https://doi.org/10.3923/mj.2019.1.7

Khan, R. M. (2013). Problem solving and data analysis using minitab: A clear and easy guide to six sigma methodology. Chennai: John Wiley & Sons.

Lieberman, G. (1965). Statistical Process Control and The Impact of Automatic Process Control. *Technometrics*, *7*(3), 283-292. https://doi.org/10.1080/00401706.1965.10490263

Mistry, M., Vaishnav, V., and Gamadia, S. (2020). Environment Monitoring, Result Evaluation and Common Contaminants Study of Vaccine Manufacturing Facility. *International Journal For Research In Applied Science And Engineering Technology*, *8*(10), 605-614. https://doi.org/10.22214/ijraset.2020.31965

Mohammed, M., and Laney, D. (2006). Overdispersion in health care performance data: Laney's approach. *Quality And Safety In Health Care*, *15*(5), 383-384. https://doi.org/10.1136/qshc.2006.017830

Moore, S., and Murphy, E. (2013). Process Visualization in Medical Device Manufacture: an Adaptation of Short Run SPC Techniques. *Quality Engineering*, *25*(3), 247-265. https://doi.org/10.1080/08982112.2013.769052

Noskievičová, D. (2013). Complex Control Chart Interpretation. *International Journal Of Engineering Business Management*, *5*, 13. https://doi.org/10.5772/56441

Prest, E., Hammes, F., van Loosdrecht, M., and Vrouwenvelder, J. (2016). Biological Stability of Drinking Water: Controlling Factors, Methods, and Challenges. *Frontiers In Microbiology*, *7*. https://doi.org/10.3389/fmicb.2016.00045

Ramirez Galindo, J. (2012). Control chart for complex systems with trended mean and non-constant variance (Doctoral dissertation). Texas Tech University.

Şengöz, N. (2018). Control Charts to Enhance Quality. In (Ed.), Quality Management Systems - a Selective Presentation of Case-studies Showcasing Its Evolution. London: IntechOpen. https://doi.org/10.5772/intechopen.73237

World Health Organization (2011). Guidelines for drinking-water quality. *WHO chronicle*, *38*(4), 104-108.

Wu, H., Zhou, Z., Zhang, Y., Chen, T., Wang, H., and Lu, W. (2012). Fluorescence-based rapid assessment of the biological stability of landfilled municipal solid waste. *Bioresource Technology*, *110*, 174-183. https://doi.org/10.1016/j.biortech.2012.01.149

Disclosures: The authors declared that there is no conflict of interest. Written informed consent from the patient form is not applicable. Ethics committee approval was not obtained as it was a case report. Author contributions**:** Concept: MEE and DEE; Design: ERR and DEE, Data Collection or Processing: ERR and MEE; Analysis/interpretation: MEE and ERR, Literature review: DEE and EER; Written by EER, Critical Review: DEE.