

General information [Signature id 383239677]

QC Number	2023/DEV-QC/001782	Client	Lerma-Quality Control
Entry date (CET)	2023-03-27	Entry time (CET)	16:52
Observation date	2023-03-25	Observation time	
Type	Action level	Reporter	Rodriguez, Gabriel (ekacy) (Gabriel Rodriguez)
Department, Division etc...	Microbiología / Microbiology		

Device/Unit(Building)**Origin of Deviation**

Short description Presencia de P.aeruginosa en PRW-04 (Stilmas)

Description

El día 25.03.23, en el Laboratorio de Microbiología, el IBT Edgar Lopez detecta, al realizar la identificación de microorganismos provenientes de los diversos monitoreos efectuados en la Planta Lerma, la presencia de Pseudomonas aeruginosa (código de Identificación: ID23-230) en el punto PRW-04 del sistema Stilmas muestreado el 23.03.23 como parte de los muestreos relacionados con el Comisionamiento de dicho sistema de agua.
Lo anterior incumple a lo indicado en el procedimiento D.06.25.40-06 (Ausencia de Pseudomonas aeruginosa en 100 mL)

Product information

Batch related No

Results affected

Results concerned Yes

Checkpoint	PRW4230323	Version	06
Test procedure	D.06.25.40	Unit	/100 ml
Requirement	Ausencia de Pseudomonas aeruginosa		

Batch**Reference to LIMS****Sample info**

Initial Reportable Result Presencia de Pseudomonas aeruginosa

Immediate CAPAs

Immediate CAPAs Mibio No

Immediate CAPAs(QC)

Responsible(QC)

Immediate CAPA(Plant)

Responsible(Plant)

Deadline Immediate CAPA

Immediate CAPAs Chemistry No

Immediate CAPAs

Laboratory errors

Laboratory error examination Yes

Laboratory errors

- A ser definido

Description laboratory errors A ser definido

Sample handling errors

Sample handling error examination Yes

Sample handling errors

- A ser definido

Description sample handling error A ser definido

Detail information

Object Water, special microorganisms

Purity level None

Sample taking from

Sample taking to

Method D.06.25.40-06

Tested place PRW4230323

Last good test date

Next test date

Information of plant No information email

Repeat sample taking Yes

Sampling design

Description

Monitorear el sitio específico en los tres días hábiles consecutivos o tres veces consecutivas al primer día hábil inmediato a la obtención del resultado, como máximo al segundo día hábil de la obtención del resultado en Nivel de Acción.

Evaluation of laboratory manager (Laboratory-/Descriptions sample handling-/Sampling error)

Error evaluation

Error evaluation other than listed Unknown

Remark/Reason

Analysis of possible reasons(MiBio)

Analysis of possible reasons are caused by MiBio

Unknown

Germ spectrum(Figure) /
Germ spectrum(Text)

Evaluation MiBio

Description of the evaluation

Evaluation (for OoS/OoT: of Phase 1)

Evaluation (for OoS/OoT: of Phase 1)

Initial Classification

Non-classified

Info mail to QP/AP

Definition of the retest

Definition of the retest design

Unknown

Repetition on

Undefined

Reason

Reason/Evaluation of the retest design

Repeat test by specifications

Deviation from repeat test
design

Unknown

Reason for deviation from
the repeat test

CAPA

Connected workflows

Electronic signatures

Signature 383239677 Signature 'Electronic signature for Reporting' by ekacy (Rodriguez, Gabriel (ekacy)) on 2023-03-27 16:52:08 id

Next step

Deadline 2023-04-27
for final
approval

Status

- In process
- Evaluation Lableader (Sanchez, Susana (messz))

Informative copy, 2023-03-28