

Report for:

**Mr. Quality Control**  
**EMLab P&K (QA)**  
1150 Bayhill Drive  
Suite 100  
San Bruno, CA 94066

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Regarding: Eurofins EPK Built Environment Testing, LLC  
Project: Sample Report  
EML ID: 1350490

Approved by:

Dates of Analysis:  
USP 797 Count & ID 26-30C: 01-20-2016  
USP 797 Count & ID 30-35C: 01-20-2016



Technical Manager  
Ariunaa Jalsrai

Service SOPs: USP 797 Count & ID 26-30C (EM-USP-S-2082, EM-USP-S-2081, EM-BT-S-1576), USP 797 Count & ID 30-35C (EM-USP-S-2082, EM-USP-S-2081, EM-BT-S-1576)

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All samples were received in acceptable condition unless noted in the Report Comments portion in the body of the report. Due to the nature of the analyses performed, field blank correction of results is not applied. The results relate only to the samples as received and tested. Information supplied by the client which can affect the validity of results: sample air volume.

Eurofins EPK Built Environment Testing, LLC ("the Company"), a member of the Eurofins Built Environment Testing group of companies, shall have no liability to the client or the client's customer with respect to decisions or recommendations made, actions taken or courses of conduct implemented by either the client or the client's customer as a result of or based upon the Test Results. In no event shall the Company be liable to the client with respect to the Test Results except for the Company's own willful misconduct or gross negligence nor shall the Company be liable for incidental or consequential damages or lost profits or revenues to the fullest extent such liability may be disclaimed by law, even if the Company has been advised of the possibility of such damages, lost profits or lost revenues. In no event shall the Company's liability with respect to the Test Results exceed the amount paid to the Company by the client therefor.

Client: EMLab P&K (QA)  
C/O: Mr. Quality Control  
Re: Sample Report

Date of Sampling: 01-10-2016  
Date of Receipt: 01-15-2016 and 01-20-2016  
Date of Report: 01-20-2016

## USP 797 - Summary of Sample Analysis Results

The summary information for each sample includes a Pass/Fail result with respect to the USP 797 action level guidelines for concentration of colony forming units (see *Table 1*) and actionable microorganisms (United States Pharmacopeia, 2014). Actionable microorganisms are defined here as Gram-negative bacteria, coagulase-positive Staphylococcus, molds, and yeasts.

**Table 1:** Recommended Action Levels for Viable Particles in Air and from Surfaces

ISO Class	Active Airborne (cfu*/m3)	Inanimate Surfaces** (cfu/plate)
5	>1	>3
7	>10	>5
8+	>100	>100

\* cfu = colony forming units

\*\* Contact plate areas vary from 24 to 30 cm<sup>2</sup>. When swabbing is used in sampling, the area covered should be at least 24 cm<sup>2</sup> but no larger than 30 cm<sup>2</sup>.

**Pass** Acceptable concentrations and absence of actionable microorganisms

**Fail** Unacceptable concentrations and/or presence of actionable microorganisms

**N/A** Not applicable. Blank Sample, insufficient sample volume and/or no ISO Class area designation provided<sup>‡</sup>

Location	Media	Type	Total CFU <sup>†</sup>	Colony Identification	ISO Class
1:	MEA	Air	< 1	No colonies detected	5
2:	TSA	Air	2	Micrococcus Staphylococcus Coagulase (+)	5
3:	MEA	Air	3	Penicillium	7
4:	TSA	Air	5	Gram-positive cocci Micrococcus	7
13:	MEA	Air	N/A	No colonies detected	None
5:	MEA	Surface	3	Aspergillus ochraceus Yeasts	5
6:	TSA	Surface	3	Bacillus Gram-negative rods	5
7:	MEA	Surface	2	Aspergillus niger Non-sporulating fungi	7
8:	TSA	Surface	ND	No colonies detected	7

<sup>†</sup> The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected.

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Location	Media	Type	Total CFU†	Colony Identification	ISO Class
14:	MEA	Surface	ND	No colonies detected	None
9:	MEA	Surface	ND	No colonies detected	5
10:	TSA	Surface	10	Bacillus Gram-negative rods Micrococcus	5
11:	MEA	Surface	3	Aspergillus niger Cladosporium Penicillium	7
12:	TSA	Surface	1	Staphylococcus Coagulase (-)	7
15:	MEA	Surface	ND	No colonies detected	None

† The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected.

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### USP 797 - Detail Sample Analysis Results

Location:	1:		2:		3:		4:	
Comments (see below)	None		None		None		None	
Area Designation	ISO Class 5		ISO Class 5		ISO Class 7		ISO Class 7	
Sample type	Andersen sample		Andersen sample		Andersen sample		Andersen sample	
Media used	MEA		TSA		MEA		TSA	
Lot#/Expiration date	123456/8-15-2016		45678/8-15-2016		123456/8-15-2016		45678/8-15-2016	
Lab ID-Version‡:	6846937-1		6846865-1		6846938-1		6846867-1	
Analysis Date	1-20-2016		1-20-2016		1-20-2016		1-20-2016	
Incubation	26° - 30°C for 5-7 days		30° - 35°C for 2-3 days		26° - 30°C for 5-7 days		30° - 35°C for 2-3 days	
	raw ct.	cfu*/m3	raw ct.	cfu*/m3	raw ct.	cfu*/m3	raw ct.	cfu*/m3
<b>BACTERIA</b>								
Gram-positive cocci							2	2
Micrococcus			1	1			3	3
Staphylococcus Coagulase (+)			1	1				
<b>FUNGI</b>								
Penicillium					3	3		
§Total	ND	< 1	2	2	3	3	5	5
Sample size	1000 liter		1000 liter		1000 liter		1000 liter	
Positive Hole	400		400		400		400	

\*cfu = colony forming units

Positive hole correction chart used for all calculations

ND = none detected

**Comments:**

Identifiers listed without a count or data entry were not detected during the course of the analysis for the respective sample.

Note: Interpretation is left to the company and/or persons who conducted the field work. Some rare strains of Staphylococcus produce free (unbound) coagulase exclusively. The applied coagulase test only measures bound coagulase.

The limit of detection is a raw count of 1. The analytical sensitivity for air samples is equal to 1 raw count divided by sample size and multiplied by the positive hole correction factor. The analytical sensitivity for surface samples is equal to 1 raw count divided by a sample size of 1 plate.

‡ A "Version" indicated by -"x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".

§ Total cfu/unit has been rounded to two significant figures to reflect analytical precision.

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### USP 797 - Detail Sample Analysis Results

Location:	13:	
Comments (see below)	None	
Area Designation	None	
Sample type	Andersen sample	
Media used	MEA	
Lot#/Expiration date	123456/8-15-2016	
Lab ID-Version‡:	6846939-1	
Analysis Date	1-20-2016	
Incubation	26° - 30°C for 5-7 days	
	raw ct.	cfu*/m3
§Total	ND	N/A
Sample size	0 liter	
Positive Hole	400	

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Positive hole correction chart used for all calculations

ND = none detected

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### USP 797 - Detail Sample Analysis Results

Location:	5:		6:		7:		8:	
Comments (see below)	None		None		None		None	
Area Designation	ISO Class 5		ISO Class 5		ISO Class 7		ISO Class 7	
Sample type	Contact plate		Contact plate		Contact plate		Contact plate	
Media used	MEA		TSA		MEA		TSA	
Lot#/Expiration date	234567/8-15-0016		567890/8-15-2016		234567/8-15-0016		567890/8-15-2016	
Lab ID-Version‡:	6846979-1		6846927-1		6846980-1		6846929-1	
Analysis Date	1-20-2016		1-20-2016		1-20-2016		1-20-2016	
Incubation	26° - 30°C for 5-7 days		30° - 35°C for 2-3 days		26° - 30°C for 5-7 days		30° - 35°C for 2-3 days	
	raw ct.	cfu*/plate	raw ct.	cfu*/plate	raw ct.	cfu*/plate	raw ct.	cfu*/plate
<b>BACTERIA</b>								
Bacillus			2	2				
Gram-negative rods			1	1				
<b>FUNGI</b>								
Aspergillus ochraceus	2	2						
Aspergillus niger					1	1		
Yeasts	1	1						
Non-sporulating fungi					1	1		
§Total	3	3	3	3	2	2	ND	ND

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Location:	14:		9:		10:		11:	
Comments (see below)	None		None		None		None	
Area Designation	None		ISO Class 5		ISO Class 5		ISO Class 7	
Sample type	Contact plate		Swab sample		Swab sample		Swab sample	
Media used	MEA		MEA		TSA		MEA	
Lot#/Expiration date	234567/8-15-0016		345678/8-15-2016		678901/8-15-2016		345678/8-15-2016	
Lab ID-Version‡:	6846981-1		6847027-1		6846999-1		6847028-1	
Analysis Date	1-20-2016		1-20-2016		1-20-2016		1-20-2016	
Incubation	26° - 30°C for 5-7 days		26° - 30°C for 5-7 days		30° - 35°C for 2-3 days		26° - 30°C for 5-7 days	
	raw ct.	cfu*/plate	raw ct.	cfu*/swab	raw ct.	cfu*/swab	raw ct.	cfu*/swab
<b>BACTERIA</b>								
Bacillus					5	5		
Gram-negative rods					2	2		
Micrococcus					3	3		
<b>FUNGI</b>								
Aspergillus niger							1	1
Cladosporium							1	1
Penicillium							1	1
§Total	ND	ND	ND	ND	10	10	3	3

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### USP 797 - Detail Sample Analysis Results

Location:	12:		15:	
Comments (see below)	None		None	
Area Designation	ISO Class 7		None	
Sample type	Swab sample		Swab sample	
Media used	TSA		MEA	
Lot#/Expiration date	678901/8-15-2016		345678/8-15-2016	
Lab ID-Version‡:	6847001-1		6847029-1	
Analysis Date	1-20-2016		1-20-2016	
Incubation	30° - 35°C for 2-3 days		26° - 30°C for 5-7 days	
	raw ct.	cfu*/swab	raw ct.	cfu*/swab
<b>BACTERIA</b>				
Staphylococcus Coagulase (-)	1	1		
§Total	1	1	ND	ND

\*cfu = colony forming units

ND = none detected

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