

Report for:

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

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)

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 cm². When swabbing is used in sampling, the area covered should be at least 24 cm² but no larger than 30 cm².

| | |
|------|---|
| 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 [¥] |

| Location | Media | Type | Total CFU [†] | Colony Identification [§] | ISO Class | Performance vs. USP 797 Guidelines [‡] |
|----------|-------|------|------------------------|------------------------------------|-----------|---|
| 1: | MEA | Air | < 1 | No colonies detected | 5 | Pass |

| | | | | | | |
|----|-----|-----|---|---|---|------|
| 2: | TSA | Air | 2 | Micrococcus Staphylococcus Coagulase (+) | 5 | Fail |
|----|-----|-----|---|---|---|------|

Reason for fail result: Total CFU result exceeds action level concentration and actionable microorganism/s detected.

| | | | | | | |
|----|-----|-----|---|--------------------|---|------|
| 3: | MEA | Air | 3 | Penicillium | 7 | Fail |
|----|-----|-----|---|--------------------|---|------|

Reason for fail result: Actionable microorganism/s detected.

| | | | | | | |
|----|-----|-----|---|---|---|------|
| 4: | TSA | Air | 5 | Gram-positive cocci <i>Micrococcus</i> | 7 | Pass |
|----|-----|-----|---|---|---|------|

| | | | | | | |
|-----|-----|-----|-----|----------------------|------|-----|
| 13: | MEA | Air | N/A | No colonies detected | None | N/A |
|-----|-----|-----|-----|----------------------|------|-----|

| | | | | | | |
|----|-----|---------|---|---|---|------|
| 5: | MEA | Surface | 3 | Aspergillus ochraceus Yeasts | 5 | Fail |
|----|-----|---------|---|---|---|------|

Reason for fail result: Actionable microorganism/s detected.

REFERENCE: United States Pharmacopeia and National Formulary Chapter <797> (USP 35-NF 30). Rockville, MD: United States Pharmacopeial Convention; 2014:40-84.

[¥] Samples that would otherwise pass in relationship to concentration and actionable microorganisms will always report as N/A when one or more bacterial colonies in the sample are identified as Other Bacteria.

[†] 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.

[§] Actionable microorganisms reported in Bold font when detected.

[‡] As stated in USP 797, the recommended action level table and actionable microorganism list are for guidance purposes only.

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USP 797 - Summary of Sample Analysis Results

| Location | Media | Type | Total CFU† | Colony Identification§ | ISO Class | Performance vs. USP 797 Guidelines‡ |
|----------|-------|---------|------------|---------------------------------------|-----------|-------------------------------------|
| 6: | TSA | Surface | 3 | Bacillus Gram-negative rods | 5 | Fail |

Reason for fail result: Actionable microorganism/s detected.

| | | | | | | |
|----|-----|---------|---|---|---|------|
| 7: | MEA | Surface | 2 | Aspergillus niger Non-sporulating fungi | 7 | Fail |
|----|-----|---------|---|---|---|------|

Reason for fail result: Actionable microorganism/s detected.

| | | | | | | |
|----|-----|---------|----|----------------------|---|------|
| 8: | TSA | Surface | ND | No colonies detected | 7 | Pass |
|----|-----|---------|----|----------------------|---|------|

| | | | | | | |
|-----|-----|---------|----|----------------------|------|-----|
| 14: | MEA | Surface | ND | No colonies detected | None | N/A |
|-----|-----|---------|----|----------------------|------|-----|

| | | | | | | |
|----|-----|---------|----|----------------------|---|------|
| 9: | MEA | Surface | ND | No colonies detected | 5 | Pass |
|----|-----|---------|----|----------------------|---|------|

| | | | | | | |
|-----|-----|---------|----|--|---|------|
| 10: | TSA | Surface | 10 | Bacillus Gram-negative rods Micrococcus | 5 | Fail |
|-----|-----|---------|----|--|---|------|

Reason for fail result: Total CFU result exceeds action level concentration and actionable microorganism/s detected.

| | | | | | | |
|-----|-----|---------|---|---|---|------|
| 11: | MEA | Surface | 3 | Aspergillus niger Cladosporium Penicillium | 7 | Fail |
|-----|-----|---------|---|---|---|------|

Reason for fail result: Actionable microorganism/s detected.

| | | | | | | |
|-----|-----|---------|---|------------------------------|---|------|
| 12: | TSA | Surface | 1 | Staphylococcus Coagulase (-) | 7 | Pass |
|-----|-----|---------|---|------------------------------|---|------|

| | | | | | | |
|-----|-----|---------|----|----------------------|------|-----|
| 15: | MEA | Surface | ND | No colonies detected | None | N/A |
|-----|-----|---------|----|----------------------|------|-----|

REFERENCE: United States Pharmacopeia and National Formulary Chapter <797> (USP 35-NF 30). Rockville, MD: United States Pharmacopeial Convention; 2014:40-84.

¥ Samples that would otherwise pass in relationship to concentration and actionable microorganisms will always report as N/A when one or more bacterial colonies in the sample are identified as Other Bacteria.

† 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.

§ Actionable microorganisms reported in Bold font when detected.

‡ As stated in USP 797, the recommended action level table and actionable microorganism list are for guidance purposes only.

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Date of Receipt: 01-15-2016
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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 |
| BACTERIA | | | | | | | | |
| Gram-positive cocci | | | | | | | 2 | 2 |
| Micrococcus | | | 1 | 1 | | | 3 | 3 |
| Staphylococcus Coagulase (+) | | | 1 | 1 | | | | |
| FUNGI | | | | | | | | |
| 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 | |

*cfu = colony forming units

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 |
| BACTERIA | | | | | | | | |
| Bacillus | | | 2 | 2 | | | | |
| Gram-negative rods | | | 1 | 1 | | | | |
| FUNGI | | | | | | | | |
| 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 |

*cfu = colony forming units

ND = none detected

Comments:

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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 |
| BACTERIA | | | | | | | | |
| Bacillus | | | | | 5 | 5 | | |
| Gram-negative rods | | | | | 2 | 2 | | |
| Micrococcus | | | | | 3 | 3 | | |
| FUNGI | | | | | | | | |
| Aspergillus niger | | | | | | | 1 | 1 |
| Cladosporium | | | | | | | 1 | 1 |
| Penicillium | | | | | | | 1 | 1 |
| §Total | ND | ND | ND | ND | 10 | 10 | 3 | 3 |

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| | | | | |
|------------------------------|----------------------------|-----------|----------------------------|-----------|
| 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 |
| BACTERIA | | | | |
| Staphylococcus Coagulase (-) | 1 | 1 | | |
| §Total | 1 | 1 | ND | ND |

*cfu = colony forming units

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Comments:

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