

# Oculer EM-Check® Surface Contamination Test

OC-ENV-06 Microbial Detection Kit



The Oculer EM-Check Surface Microbial Detection Kit is an all-inclusive, ready-to-use kit which simplifies and quickens the process of environmental surface testing for biological contamination. The kit uses Oculer's Rapid 930 Series Technology for the automated detection of microbial activity on cleanroom surfaces using a design that reduces the likelihood of sample cross-contamination and mishandling of samples by the operator.

The OC-ENV-02 kit is intended to be used with the Oculer 930 Series automated reader. The reader's internal LED sends light to the polymer sensor located in the kit vial. The optical system detects the decay of the fluorescence signal emission, which correlates to the oxygen depletion over time due to the respiration of microorganisms in the sample. The system is flexible and allows either enumeration produced from an internal calibration, or a pass/fail test based on presence/absence of oxygen depletion over time. The instrument software allows continuous measurements of oxygen depletion within the reader or endpoint measurements from externally incubated samples.

The OC-ENV-02 kit with Oculer's dedicated reader offers:

- A traditional, growth-based method with enhanced sensitivity due to the oxygen sensing technology
- Non-destructive testing allows further analysis or speciation by traditional methods
- Suitability for Class A/ISO 5 classified areas and lower
- An ideal way to sample the most critical and hard-to-reach points identified by risk assessment
- High recovery of surface microbial contaminants using certified flocked swabs
- Faster time-to-result by using an oxygen-sensitive probe assay
- Automated sample analysis eliminating human reading subjectivity
- Up to 24 samples can be automatically processed per carousel

## BENEFITS

### Time-to-Result

- Achieve results typically within 24 hours
- Increase sensitivity by maximising recovery
- Advanced test tracking and reliability

### Cost Saving

- Easier disposal than agar plates
- No extra costs and risks due to reagent dispensing
- Reduces risks of false positives in aseptic production areas and related investigations

### Test Ready

- Fully prepared and disposable
- Minimizes operator handling
- Eliminates unintended contamination

### Reduced Operator Handling

- Decreases time-consuming and operator-dependent manipulations
- Simplified standard operating procedures
- Faster sampling steps
- Easy lift-out interchangeable carousel

## FEATURES

- Standard TSB culture media
- FLOQSwab™ flocked swab with SRK™ for highest recovery swabbing (>70% each lot).
- Reduced variability on results
- Eliminate cleaning validation studies for culture media residues required for contact plate method
- Compact design and low maintenance reader
- Integrated incubator
- Intuitive screen monitor
- Easy-to-read dashboard with tabular graphics
- Result as Presence/Absence or as colony forming units (CFU)
- Secure results and 21 CFR part 11 and EU GMP Annex 11 compliance
- Compatible with Microsoft Windows 10®

## APPLICATIONS

- Microbiological surface sampling in cleanrooms and associated controlled environments
- Microbiological monitoring of equipment, operator clothing and gloves
- Easy monitoring of critical point in RABS and isolators

*Bringing Microbiology to Light*

# Ocüler EM-Check® Surface Contamination Test

OC-ENV-06 Microbial Detection Kit - SPECIFICATIONS



## Surface Detection Kit

<b>Materials</b>	Each individual gamma irradiated peel pouch kit contains: - EM-Check® Vial: polypropylene vial with integrated platinum porphyrin polymer and 10 ml of TSB - FLOQSwab: flocked swab in polypropylene tube with sponge and 1ml of Surface Rinse Kit™ (SRK)	
<b>Dimensions</b>	EM-Check® Vial - 15 ml capacity vial: - 120 mm length including red stopper - 17 mm diameter	Swab tube: - 175 mm total length including green stopper - 12 mm external diameter
<b>Filling Volume</b>	10 ml	
<b>Media</b>	Tryptic Soy Broth (TSB)	
<b>Additives</b>	Neutralizers included in the SRK buffer	
<b>Packaging Option</b>	Two bags containing five kits each are triple-bagged together, 20 of the triple-bagged units are placed inside a fourth plastic bag to produce a final package containing a total of 200 vial kits.	
<b>Storage Temperature</b>	5 °C - 25 °C (41 °F to 77 °F)	
<b>Approximate Detection</b>	10 <sup>0</sup> to 10 <sup>8</sup> cells	

## Ocüler Rapid 930 Series Automated Reader

<b>Model</b>	Model 930-15 uses 15 ml capacity vials or adapters	<b>Operating Temperature</b>	18 °C to 24 °C (64.4 °F to 75.2 °F)
<b>Test capacity</b>	24 vials	<b>Storage Temperature</b>	10 °C to 35 °C (50 °F to 95 °F)
<b>Throughput</b>	Up to 216 tests in pass/fail mode	<b>Relative Humidity</b>	0 - 95% non-condensing
<b>Power (adaptor supplied)</b>	100-240 VAC, 50-60 Hz Output 72 W max	<b>Dimensions (H x W x D)</b>	31.8 x 30.50 x 38.14 cm (12.52 x 12.01 x 15.02 in)
<b>USB ports</b>	1 USB peripheral port 1 external Barcode Reader port	<b>Weight</b>	12.30 kg (27.12 lbs)
<b>Internal Incubation Temperature</b>	Ambient 2 °C to 40 °C (35.6 °F to 104 °F)	<b>Accessories</b>	Laptop computer (pre-loaded with Ocüler software), extra carousel (24 places), external Barcode Reader
<b>Language</b>	Manageable by end-user		

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