

Oxyrase[®] – Nature's Antioxidant[®]

December 2015

Dear Valued Customer,

Thank you for your interest in OxyPRAS Plus[®] and OxyPlate[™] plated media. To assist you with your IQCP requirements I am providing this letter for your files.

The approved CLSI Standard M22-A3 specifies the requirements for Quality Control of commercially prepared culture media by breaking it into two categories: EXEMPT and NONEXEMPT. EXEMPT media does not need to be retested provided that the manufacturer certifies the media has met all criteria and the laboratory has not deemed it necessary to perform complete quality control. All current OxyPRAS Plus[®] and OxyPlate[™] media (listed below) is considered EXEMPT:

- OxyPRAS Plus[®] Brucella Blood Agar
- OxyPRAS Plus[®] KVL Agar

- Modified Columbia Agar
- AnaSelect[®] Blood Agar Plate
- AnaSelect[®] OxyPlate[™]

- OxyPRAS Plus[®] BBE Agar
- OxyPRAS Plus[®] BBE/KVL Bi-Plate

OxyPRAS Plus[®] PEA Blood Plate

- Schaedler Blood Agar OxyPlate™
- KVL OxyPlate[™]

Furthermore, all lots of OxyPRAS Plus[®] and OxyPlate[™] plated media have the following characteristics:

- i. The Certificate of Analysis (COA), provided with each lot, certifies that the lot has met or exceeded established performance criteria. Each COA provides the data from our QC testing that meets or exceeds the testing required by the CLSI Standard M22-A3.
- ii. Our recommendations for user QC can be found in the Product Inserts online at <u>www.oxyrase.com/technical-information</u>. Product Inserts indicate that each lot is tested and has performed acceptably according to Oxyrase, Inc.'s specifications which minimally include the CLSI Standards M22-A3. We do not require end user QC unless the specific laboratory has deemed it necessary.
- iii. Any alerts or product updates are supplied directly to customers, for their records, as needed.

Please feel free to contact us with any questions or concerns.

Regards,

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Jeff Little Quality Manager