Purpose: To define an Individualized Quality Control Plan (IQCP) for OxyPRAS Plus® Brucella media supplied by Oxyrase, Inc. to meet the requirements of the Centers for Medicare and Medicaid Services (CMS) and the College of American Pathologists (CAP).

Scope: This IQCP applies to all laboratory personnel utilizing this commercially prepared media.

Background Information:

I. Regulatory Guidelines
   a. 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.
      i. Oxyrase, Inc. OxyPRAS Plus® Brucella Blood Agar Plates are categorized as EXEMPT by CLSI.
      ii. Oxyrase, Inc. provides a lot specific Certificate of Analysis that certifies the lot has met or exceeded established performance criteria.

II. CAP Accreditation Requirements
   a. The College of American Pathologists (CAP) indicates that laboratories may implement an IQCP, for commercially prepared media that is EXEMPT per the CLSI M22-A3 Standard, accepting QC performed by the media supplier. The media supplier's records must be maintained and show that the QC performed meets the CLSI/NCCLS standard.
      i. Each Oxyrase, Inc. lot specific Certificate of Analysis provides the data from their QC testing indicating the lot meets or exceeds the testing required by the CLSI Standard M22-A3.
      ii. Oxyrase, Inc. provides a lot specific Certificate of Analysis with each shipment.
   b. Question 42 of the April 2015 revision of FAQ's for IQCPs found on the CMS website states in part: "laboratory documentation showing visual quality checks of media are acceptable in house data. The laboratory may also include manufacturer's quality certificates as part of the information considered in its risk assessment."
      i. We maintain all supplier CoAs, alerts, and product updates for each lot of media.
      ii. We perform in-house visual checks of the media prior to use.

III. Manufacturer Instructions
      i. Oxyrase, Inc. Product Inserts can be found online at: http://www.oxyrase.com/technical-information/product-inserts
      ii. Oxyrase, Inc. has no recommendation for end user QC on EXEMPT media. Unless the laboratory has deemed it necessary.

iii. Oxyrase, Inc. Product Inserts state that each lot is tested and performed acceptably according to their specifications which include CLSI Standards M22-A3.
iv. Oxyrase, Inc. supplies alerts and product updates directly to users as needed.

Summary of Historical In-House Data:
CLSI exempt anaerobe media is inspected for cracked plates, cracked agar, unequal or uneven agar surface, hemolysis, freezing, bubbles/pits, oxidation, color change, and contamination. Additionally technicians look for unusual contamination and abnormal growth when reviewing cultured samples that may indicated an issue with the plated media.

OxyPRAS Plus® Brucella media has been used since 2005. A review of historical quality data was collected for the period 9/1/2014 – 9/1/2015 and found:

- Unacceptable quality was noted on <0.1% of the media inspected during the specified timeframe.

THIS SPACE INTENTIONALLY LEFT BLANK

Risk Assessment:

Risk Assessment Matrix (example only)

Category	Failure Mode	Frequency	Severity	Risk Mitigation Steps
Pre-Analytical	Specimen Collection	Occasional	**Critical**	SOP.AAAA defines the process for collecting, identifying and traceability requirements for patient specimens.
	Specimen Container	Uncommon	Minor	SOP.BBBB defines acceptable specimen containers
	Specimen Storage	Uncommon	Minor	SOP.CCCC defines acceptable specimen storage
	Specimen Characteristics	Uncommon	Minor	SOP.AAAA defines the process for collecting, identifying and traceability requirements for patient specimens.
Operator	Competency	Uncommon	**Critical**	All testing personnel are trained and deemed competent. This is the responsibility of the respective Supervisor.
	Training	Uncommon	**Critical**	All testing personnel are trained and deemed competent. This is the responsibility of the respective Supervisor.
	Resources	Occasional	Minor	Assure appropriate staffing for inspection and use of plated media.
	Proficiency Testing	Occasional	Minor	Assure PT failures are investigated and corrective actions are implemented.
Supplies Test System	Receiving Inspection	Uncommon	Minor	Media is received, inspected and stored according to SOP.DDDD and Manufacturer's Instructions
	Expired Materials	Uncommon	Minor	Stock of plated media is routinely checked. All media is used within expiration dates or discarded.
	Inspection	Uncommon	Minor	Inspection requirements are defined per SOP.EEEE
	Failure / Contamination	Uncommon	Minor	Inspection requirements are defined per SOP.EEEE and Visual quality checks are performed.
	Growth	Uncommon	Minor	Controls and training are in place to verify that adequate growth is acceptable. Discrepant results are reviewed with the Supervisor.
Environment	Utilities	Uncommon	Negligible	Adequate utilities are maintained for required laboratory operation.
	Facility	Uncommon	Negligible	Adequate facilities and environments are maintained for required laboratory operation.
	Equipment	Uncommon	Minor	Preventative Maintenance and Service Contracts are in place for all required equipment.
Results	Result Release	Uncommon	Negligible	All results are reviewed before release.
	Clinician Feedback	Uncommon	**Critical**	All responses and complaints from Clinicians are re-viewed and investigations/corrective actions taken as necessary.

Quality Control Plan:

The Individualized Quality Control Plan (IQCP) for OxyPRAS Plus® Brucella media supplied by Oxyrase, Inc. is:

- Inspect media, upon receipt or prior to use, for: cracked plates, cracked agar, unequal or uneven agar surface, hemolysis, freezing, bubbles/pits, oxidation, color change, and contamination.
    - Document acceptance on the lot specific Certificate of Analysis in the box provided.
- Inspect media prior to use for potential contamination.
- Inspect media for unusual contamination and abnormal growth when reviewing cultured specimens.
- Maintain Supplier Certificate of Analysis with QC data and receiving inspection documentation on file.
- Maintain Supplier product inserts, alerts and product updates on file.
- Immediately notify Shift Supervisor of any failures.
- As directed, conduct an investigation, determine root cause, implement corrective action and if required notify Supplier.

Quality Assessment:

To continually monitor the effectiveness of our IQCP we will:

- Monitor and trend data collected during the IQCP
- Review and revise IQCP and acceptance criteria annually as necessary.
- Conduct training and competency assessment annually or as needed.

Approval:

This Individualized Quality Control Plan has been reviewed and approved by:

Lab Director: _____ Date: _____