

	<p style="text-align: center;">Cycle Development Protocol Table of Contents ONLY For Website</p>	Page 1 of 3
		Document No. / Revision No. CD-WEB-TOC, Rev. 1
		Revision Date / Initials 18-Jan-14 / RDN

Cycle Development Protocol

Table of Contents ONLY

For Website

<p>Contents, design and layout of this document are the CONFIDENTIAL property of Ardien Consulting Services LLC. Any dissemination, distribution, or copying in its entirety or partially is strictly prohibited.</p>

Table of Contents

	Title Page.....	1
	Table of Contents.....	2 – 3
1.0	SIGNATURE LOG.....	4
2.0	PROTOCOL REVIEW AND APPROVAL.....	5
3.0	PURPOSE.....	6
4.0	SCOPE.....	7
5.0	DEFINITIONS.....	8 – 13
5.1	Acronyms.....	8 – 11
5.2	Terms and Definitions.....	12 – 13
6.0	SYSTEM DESCRIPTION.....	14
7.0	POINTS TO CONSIDER.....	15
8.0	EQUIPMENT AND MATERIALS.....	15
8.1	Equipment.....	15
8.2	Materials.....	15
9.0	PROCEDURE STEPS.....	15
10.0	DELIVERABLES.....	15
11.0	ATTACHMENTS.....	15
12.0	REFERENCES.....	16 – 18
13.0	PREREQUISITES AND APPROVAL TO PROCEED WITH PROTOCOL EXECUTION.....	19
14.0	PARAMETERS THAT AFFECT VPHP BIODECONTAMINATION EFFICACY.....	20
15.0	RATIONALE.....	21 – 31
16.0	PROCEDURE.....	32 – 132
16.1	Document Execution.....	32
16.2	Document Completion.....	32
16.3	Test Procedure.....	32 – 34
16.4	Test Plan 1 - Isolator Instrument Calibration Verification.....	35 – 40
16.5	Test Plan 2 - Test Instrument Calibration Verification.....	41 – 45
16.6	Test Plan 3 - Material Verification.....	46 – 50
16.7	Test Plan 4 - Biological Enumeration.....	51 – 63
16.8	Test Plan 5 - Challenge Locations.....	64 – 66
16.9	Test Plan 6 - Cycle Parameters.....	67 – 78
16.10	Test Plan 7 - Pre-Operation Checklist.....	79 – 84
16.11	Test Plan 8 – Cycle Run Checklist.....	85 – 88
16.12	Test Plan 9 - D-Value Analysis Results.....	89 – 100
16.13	Test Plan 10 - Temperature Profile Results.....	101 – 107
16.14	Test Plan 11 - Chemical Indicator Profile Results.....	108 – 112
16.15	Test Plan 12 - Biological Indicator Profile Results.....	113 – 121
16.16	Test Plan 13 - VPHP Concentration Sensing System Results.....	122 – 125

	<p style="text-align: center;">Cycle Development Protocol Table of Contents ONLY For Website</p>	Page 3 of 3
		Document No. / Revision No. CD-WEB-TOC, Rev. 1
		Revision Date / Initials 18-Jan-14 / RDN

16.17	Test Plan 14 - Aeration Analysis Results.....	126 – 132
17.0	CHANGE REQUEST LOG.....	133
18.0	LIST OF ATTACHMENTS.....	134
19.0	PROTOCOL COMPLETION LOG.....	135
20.0	PROTOCOL EXCEPTION REPORT.....	136 – 137
	Protocol Exception Report List.....	138
	Change Record.....	1 of 1