

Revision	Date	Team Members	Description of Change
1	3/10/23	All	Creation of risk analysis, risk control, risk/ benefit analysis, information/comments

Severity Ratings	Description	Example	Occurrence Ratings	Description	Example
5 catastrophic		severe allergic reaction due to high gluten levels undetected (above X ppm)	5 frequent		nearly always (<95% of the time)
4 critical		moderate allergic reaction due to moderate gluten undetected (X-X ppm gluten)	4 probable		very likely (50-95% of the time)
3 serious		minor allergic reaction due to cross-contamination undetected (0-Xppm)	3 occasional		likely (10-50% of the time)
2 minor		unclear results, food not eaten out of caution	2 remote		unlikely (1-10% of the time)
1 negligible		false positive, food not eaten	1 improbable		almost never (<1% of the time)

Item Number	Function	Risk Analysis							Risk Control				Risk/Benefit Analysis	Information/Comments	
		Functional Output	HAZARD (Potential cause of Hazard)	Hazardous Situation	HARM (Potential adverse effect)	Cause	SEVERITY	OCCURRENCE	RPN	RISK MITIGATION	SEVERITY	OCCURRENCE			RPN
1	Chemical Contamination	Device emits harmful chemicals	Harmful chemicals injected	User has a reaction to injecting toxic chemicals	Material deteriorates or malfunctions	5	1	5	Material specification on the biocompatibility	5	1	5	afap	Yes	Label for chemical risk
2	Unclear Display	Device inaccurately does not detect gluten or shuts off in the middle of analyzing the sample	False negative result displayed	User has reaction after eating the contaminated food	Low power or device performing antibody test malfunctions	4	2	8	Alert when power is low clearly on display for user	4	1	4	afap	Yes	Manual of alerts
3	Electrical Shock	Device produces current in the wrong location	Electrical current exposed	User gets minorly electricuted	Electrical malfunction	4	1	4	Ensuring all electrical codes are met: including proper covering of all wires	4	1	4	afap	Yes	Label for electrical shock risk
4	Physical Contamination	Device material breaks off and creates small fragements	Small fragement ingested which harms the digestive system	Fragment causes bockage requiring surgery	Material is not durable or user uses too much force	3	1	3	Material specification on durability and flexibility of material	3	1	3	afap	Yes	Label for material damage risk
5	False Negative	Antibody test not working correctly	Gluten-containing food injected	User is unable to obtain results	Insufficient amount of sample provided or antibodies not working properly	5	2	10	Alert to user when sample does not meet a minimum weight or that antibody test isn't working	5	1	5	afap	Yes	Manual of alerts
6	False Positive	Antibody test not working correctly	Gluten free food is not injected	User is left hungry	Prior contamination from a previous test, not enough antibodies working correctly	2	3	6	Alert user that there is contamination from the last sample or that the antibody test is malfunctioning	2	2	4	afap	Yes	Manual of alerts

FINAL	Overall Residual Risk is Acceptable (Yes/No):											Yes
-------	---	--	--	--	--	--	--	--	--	--	--	-----