

Form sGnRHa/Ovaplant-3: Results Report Form

For Use in sGnRHa (Ovaplant®) Clinical Field Trials Conducted under sGnRHa INAD 11-375

INSTRUCTIONS

- Investigator must fill out Form sGnRHa/Ovaplant-3 no later than 10 days after completion of the study period. Study Number must be recorded on all pages of Form sGnRHa/Ovaplant-3. Attach lab reports and other information.
- If salmon gonadotropin releasing hormone analog was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
- Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO for inclusion in the permanent file.
- Note:** Both Investigator and Study Monitor should sign and date Form sGnRHa/Ovaplant-3.

SITE INFORMATION

Facility	Fish Hatchery A
Reporting Individual	John Doe

FISH CULTURE AND DRUG TREATMENT INFORMATION

Drug lot number	111000	Total amount drug used (mg)	5.7
Fish species treated	Steelhead trout	Water temperature (°F)	50.0
Drug dosage - males (ug/kg body wt)	40	Drug dosage - females (ug/kg body wt)	40
Average fish weight (gm)	3,200	Average fish length (in)	30.0
Number of treated males	29	Number of treated females	26
Number of control males	20	Number of control females	20
Treatment date(s)		3/5; 3/10; 3/25/08	
Treatment method	Pellet Implant	Pellet size (i.e., ug sGnRHa per pellet)	75 (male) & 150 (female)
Number of pellets per male	1	Number of pellets per female	1
Spawning/evaluation interval (time from treatment until spawning)	Every 7 days	Spawning/evaluation date(s)	3/12 – 4/8/08

sGnRHa/Ovaplant® Results Record - Females

INSTRUCTIONS

1. "Ripe" females are those fish that have ovulated or released their eggs. "None-ripe" fish are the converse.
2. Use additional copies of Results Record for additional fish treated.

Be sure the facility name is written here:

		sGnRHa TREATED FISH - Females					CONTROL FISH - Females				
Fish #	Date Treated	Date Evaluated	Ripe	Non-ripe	% Eye-up	% Hatch	Date Evaluated	Ripe	Non-ripe	% Eye-up*	% Hatch*
1	3/5/08	3/12/08	yes		95.4	85	3/12/08	yes		93.2	82
2	3/5/08	3/12	Yes		97.0	80	3/12	Yes		96.2	70
3	3/5	3/12	Yes		76.2	83	3/19		Yes	-	-
4	3/5	3/12	Yes		50.0	75	3/19		Yes	-	-
5	3/5	3/19	Yes		89.1	95	3/19	Yes		93.5	89
6	3/5	3/19	Yes		99.1	96	3/19	Yes		16.8	92
7	3/5	3/19	Yes		0.0	-	3/19	Yes		98.0	75
8	3/10	3/17	yes		95.7	75	3/24	yes		92.3	95
9	3/10	3/17	Yes		99.3	85	3/24		Yes	-	-
10	3/10	3/17	Yes		96.6	86	3/24		Yes	-	-
11	3/10	3/17	Yes		41.9	86	3/24	yes		76.1	48
12	3/10	3/17	Yes		83.3	81	3/24		Yes	-	-
13	3/10	3/24	Yes		23.0	89	3/24	Yes		85.5	98
14	3/10	3/24	Yes		89.7	94	3/24	Yes		89.5	28
15	3/10	3/24	Yes		96.9	85	4/1	yes		45.0	98
16	3/10	3/24	Yes		21.6	96	4/1		Yes	-	-
17	3/25	4/1	Yes		86.1	74	4/1		Yes	-	-
18	3/25	4/1	yes		96.9	86	4/8	Yes		98.5	78
19	3/25	4/1	Yes		95.3	96	4/8	Yes		96.9	79
20	3/25	4/8		No	-	-	4/8	Yes		98.5	85

* If eggs from multiple females have been combined during incubation, indicate data from combined egg lots with a vertical line "connecting" all females contributing to a single egg lot

sGnRH_a/Ovaplant® Results Record - Males

INSTRUCTIONS

1. "Ripe" males are those fish that are actively spermiating. "None-ripe" males are the converse.
2. Use additional copies of Results Record for additional fish treated.

Be sure the facility name is written here:

		sGnRH _a TREATED FISH - Males					CONTROL FISH - Males				
Fish #	Date Treated	Date Evaluated	Ripe	Non-ripe	Milt/fish (ml)	Motility Score	Date Evaluated	Ripe	Non-ripe	Milt/fish (ml)	Motility Score
1	3/5/08	3/12/08	yes		20	Nd	3/12/08	yes		1	0
2	3/5/08	3/12	Yes		20	Nd	3/12	Yes		5	3
3	3/5	3/12	Yes		20	Nd	3/19		Yes	-	-
4	3/5	3/12	Yes		50	3	3/19		Yes	-	-
5	3/5	3/19	Yes		10	4	3/19	Yes		5	4
6	3/5	3/19	Yes		55	4	3/19	Yes		8	4
7	3/5	3/19	Yes		25	3	3/19	Yes		10	4
8	3/10	3/17	yes		15	2	3/24	yes		15	4
9	3/10	3/17	Yes		30	4	3/24		Yes	-	-
10	3/10	3/17	Yes		10	3	3/24		Yes	-	-
11	3/10	3/17	Yes		50	3	3/24	yes		20	3
12	3/10	3/17	Yes		50	4	3/24		Yes	-	-
13	3/10	3/24	Yes		30	Nd	3/24	Yes		25	4
14	3/10	3/24	Yes		30	Nd	3/24	Yes		25	2
15	3/10	3/24	Yes		50	Nd	4/1	yes		30	3
16	3/10	3/24	Yes		30	4	4/1		Yes	-	-
17	3/25	4/1	Yes		50	3	4/1		Yes	-	-
18	3/25	4/1	yes		50	2	4/8	Yes		40	1
19	3/25	4/1	Yes		30	Nd	4/8	Yes		50	3
20	3/25	4/8		No	-	4	4/8	Yes		15	2

RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol? Attach pathology reports; Both Pre-and Post-Treatment.

Treatment appeared to be successful. Percent ovulation in treated fish was 96%; as compared to 65% in the control females. Percent spermiation in the male fish was 97%; as compared to 65% in the control males. Males milt volume was, on average, improved over the control. Females generally spawned within 2 weeks of the implant with no evidence of poor quality gamets.

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

none

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period :	JD	Fish treated with sGnRH_a (Ovaplant[®]) may not be stocked, released, or harvested for human consumption. All treated fish must ultimately be destroyed. Investigator should initial here to indicate compliance with disposition requirements of sGnRH_a (Ovaplant[®]) treated fish
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 NEGATIVE REPORT Salmon gonadotropin releasing hormone analog (Ovaplant[®]) was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared:	4/15/08	Investigator:	Sign here
Date Reviewed:	4/15/08	Study Monitor:	Sign here

sGnRHa Treatment Summary Information - Females
(To be completed by the NIO)

Treated Females							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	% Eye-up	% Hatch

Control Females							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	% Eye-up	% Hatch
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			

sGnRH α Treatment Summary Information - Males

(To be completed by the NIO)

Treated males							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	Milt/fish (ml)	Motility Score

Control Males							
Fish #s	Number of fish	Date Treated	Date Evaluated	Interval between treatment and evaluation (specify hours or days)	% Ripe	Milt/fish (ml)	Motility Score
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			
		XXXX		XXXX			