

Form LHRHa – 3: Results Report Form For Use of Luteinizing Hormone-Releasing Hormone Analog Under INAD 8061

INSTRUCTIONS

1. Investigator must fill out Form LHRHa-3 no later than 10 days after completion of the study period. Study Number must be recorded on all pages of Form LHRHa-3. Attach lab reports and other information.
2. If Luteinizing Hormone-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.
3. 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 AADAP Office for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form LHRHa-3.

SITE INFORMATION

Facility	Fish Hatchery A
Reporting Individual	John Doe

FISH CULTURE AND DRUG TREATMENT INFORMATION

Drug lot number	1111	Total amount drug used (mg)	20
Fish species treated	paddlefish	Water temperature (°F)	62.0
Drug dosage male (ug/kg body wt)	20	Drug dosage female (ug/kg body wt)	100
Average fish weight (gm)	27,216	Average fish length (in)	40
Number of treated males	5	Number of treated females	9
Number of control males	0	Number of control females	3
Treatment dates		4/18/08; 4/21/08	
Injection Type (i.e. IM or IP)	ip	Injection interval (hrs or days)	12 hrs
Number of injections/males	1	Number of injections/females	2
Spawning/evaluation interval (time from treatment until spawning)	24 hrs	Spawning/evaluation date	4/19/08 - 4/23/08

Hormone Results Record - Version 4

INSTRUCTIONS

1. Green females are those fish that have not ovulated or released their eggs, green males are those fish that are not actively spermiating.
2. Motility Score based on a scale of 0 - 4 (see Study Protocol Section VI).
3. Use additional copies of this form for additional treatment days.

Be sure the facility name is written here:

		TREATED FISH - Females						CONTROL FISH - Females					
Date Treated	Date Evaluated	# of Fish	Number Ripe	Number Green	% Ripe	% Eye-Up	% Hatch	Number of Fish	Number Ripe	Number Green	% Ripe	% Eye-up	% Hatch
4/18/08	4/19 - 20	6	6	0	100	70	90	0					
4/21/08	4/22 - 23	3	2	1	67	80	90	3	1	2	33	65	80

		TREATED FISH - Males						CONTROL FISH - Males					
Date Treated	Date Evaluated	# of Fish	Number Ripe	Number Green	% Ripe	Milt/ fish (mL)	Motility Score	# of Fish	Number Ripe	Number Green	% Ripe	Milt/ fish (mL)	Motility Score
4/18/08	4/19 - 20	3	3	0	100	50	4	0					
4/21/08	4/22 - 23	2	1	1	50	25	3	0					

STUDY NUMBER 8061-08-XXX

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 females was between 67 – 100%; as compared to 33% in the control females. Percent spermiation in treated males was between 50 – 100%; no control males were used. The male that did not spermiate was determined to be an immature male.

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

none

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period : no withdrawal period x 14 days no release

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). 70 days



NEGATIVE REPORT Luteinizing Hormone-Releasing Hormone Analog 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: 4/30/08

Investigator: Sign here

Date Reviewed: 4/30/08

Study Monitor: Sign here