GENESYS Diagnostics INC.

PATIENT INFORMATION		SPECIMEN DETAILS		PROVIDER INFORMATION
NAME:	[redacted]	SPECIMEN TYPE:	[redacted]	[redacted]
ACC #:	[redacted]	COLLECTION DATE:	[redacted]	
DOB:	[redacted]	RECEIVED DATE:	[redacted]	
SEX:	[redacted]	REPORT DATE:	[redacted]	

Pharmacogenetic Pain Report

Current Patient Medications

Lidocaine, Prazosin, Fentanyl, Percocet, Atorvastatin, Clonazepam, Seroquel

Percocet
Oxycodone

Possible Altered Response to Oxycodone (CYP2D6: Poor Metabolizer) — ACTIONABLE

Decreased conversion of oxycodone to the more active metabolite oxymorphone is expected in CYP2D6 poor metabolizers. However, there is insufficient evidence whether poor metabolizers have decreased analgesia when taking oxycodone. Adequate pain relief can be achieved by increasing the dose in response to pain symptoms. Other opioids not metabolized by CYP2D6 may also be considered (i.e., morphine, oxymorphone, buprenorphine, fentanyl, methadone, and hydromorphone).

Atorvastatin
Lipitor

Normal Myopathy Risk (SLCO1B1: Normal Function) — INFORMATIVE

Atorvastatin plasma concentrations are not expected to increase, and unless other genetic or circumstantial risk factors are present, atorvastatin can be prescribed at standard FDA-recommended starting doses and adjusted based on disease -specific guidelines. (Other myopathy predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, renal impairment, high statin dose, comedications, and female gender.)

Atorvastatin
Lipitor

Normal Response to Atorvastatin (CYP3A4: Normal Metabolizer) — INFORMATIVE

The genotype result indicates that the patient does not carry the CYP3A4*22 allele (this allele is associated with a decreased CYP3A4 enzyme activity). The patient is expected to achieve an optimal lipid control goal with standard atorvastatin dose requirements.

Clonazepam
Klonopin

Normal Response to Clonazepam — INFORMATIVE

Pharmacogenetic guidance: No genetically guided drug selection or dosing recommendations are available.
Polypharmacy guidance: clonazepam is extensively metabolized by CYP3A4 to an amino metabolite that is further acetylated by N-acetyltransferases. This drug should be used with caution when prescribed with CYP3A4 inhibitors or inducers.

Fentanyl
Actiq

Good Response to Fentanyl (OPRM1: Normal OPRM1 Function) — INFORMATIVE

The patient does not carry the OPRM1 118A>G mutation. Acute postoperative and cancer pain: the patient is expected to experience good analgesia at standard fentanyl doses. Because fentanyl has a narrow therapeutic window, it is advised to carefully titrate this drug to a tolerable dose that provides adequate analgesia with minimal side effects.

Seroquel
Quetiapine

Normal Response to Quetiapine — INFORMATIVE

Pharmacogenetic guidance: Quetiapine is predominantly metabolized to several metabolites by CYP3A4. CYP3A5 and CYP2D6 are also responsible for quetiapine metabolism but their role in the overall metabolism of this drug is minor compared to CYP3A4. N-desalkylquetiapine, a pharmacologically active metabolite (responsible of the antidepressant effect) is further metabolized by CYP2D6 and CYP3A4. Preliminary studies have shown that genetic polymorphisms of CYP3A4, CYP2D6 and CYP3A5 enzymes may be responsible in variable exposures to quetiapine and to its active metabolite N-desalkylquetiapine. However, the clinical significance of these changes is not established yet and no genetically guided drug selection or dosing recommendations are available. Quetiapine dose should be titrated based on the clinical response and tolerability of the individual patient. **Polypharmacy guidance**: Quetiapine dose should be reduced to **one sixth of original dose** when co-medicated with a potent CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, indinavir, ritonavir, nefazodone). When the CYP3A4 inhibitor is discontinued, the dose should be increased by 6 fold. Quetiapine dose should be increased up to 5 fold of the original dose when used in combination with a chronic treatment (e.g. > 7-14 days) of a potent CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, St. John's wort etc.). When the CYP3A4 inducer is discontinued, the dose should be reduced to the original level within 7-14 days.

Medications outside the scope of the report: Lidocaine, Prazosin

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A medication has potentially reduced efficacy, increased toxicity or the patient has an increased risk for the indicated condition.	**ACTIONABLE**	Recommendations based upon publications by international pharmacogenetic expert groups, consortia or regulatory bodies (CPIC, DPWG, FDA, EMA). Recommendations are suitable for implementation in a clinical setting. Guidelines may change as knowledge arises.
Guidelines exist for adjusting dosage, increased vigilance or the patient has a moderate risk for the indicated condition.		
The medication can be prescribed according to standard regimens or the patient's risk for the indicated condition is not increased.	**INFORMATIVE**	There are insufficient or contradictory findings documenting the impact of a given genetic polymorphism or drug interaction. Recommendations are informative and implementation in a clinical setting is optional.

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Risk Management

✓ Hyperhomocysteinemia - Thrombosis

No Increased Risk of Hyperhomocysteinemia

The patient carries one MTHFR C677T mutation and one A1298C mutation (compound heterozygous). MTHFR enzyme activity is reduced.

The patient's reduced MTHFR activity is not a risk factor for hyperhomocysteinemia. Unless other risk factors are present, the patient is not expected to have an increased risk for venous thromboembolism (VTE).

Testing total plasma homocysteine level may be beneficial. Hyperhomocysteinemia can be treated with nutritional supplementation.

✓ Thrombophilia

No Increased Risk of Thrombosis

The patient does not carry the Factor V Leiden G1691A mutation or Factor II G20210A mutation (wild-type).

The patient's risk of thrombosis is not increased (average risk of clotting is about 1 in 1000 for anyone in a year). However, because this test cannot find all of the inherited reasons for abnormal clotting, other factors may affect this risk assessment.

Unless other genetic and/or circumstantial risk factors are present (e.g., smoking or obesity...), estrogen-containing contraceptive and hormone replacement therapy can be used by the patient.

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Potentially Impacted Medications

CATEGORY	DRUG CLASS	STANDARD PRECAUTIONS	USE WITH CAUTION	CONSIDER ALTERNATIVES
Pain	Fibromyalgia Agents	Milnacipran (Savella)		
	Muscle Relaxants	Carisoprodol (Soma) Cyclobenzaprine (Flexeril, Amrix) Metaxalone (Skelaxin) Methocarbamol (Robaxin)	Tizanidine (Zanaflex)	
	NSAIDs	Celecoxib (Celebrex) Diclofenac (Voltaren) Flurbiprofen (Ansaid) Ibuprofen (Advil, Motrin) Indomethacin (Indocin) Ketoprofen (Orudis) Ketorolac (Toradol) Meloxicam (Mobic) Nabumetone (Relafen) Naproxen (Aleve) Piroxicam (Feldene) Sulindac (Clinoril)		
	Opioids	Alfentanil (Alfenta) Buprenorphine (Butrans, Buprenex) Dihydrocodeine (Synalgos-DC) Fentanyl (Actiq) Hydromorphone (Dilaudid, Exalgo) Levorphanol (Levo Dromoran) Meperidine (Demerol) Morphine (MS Contin) Oxymorphone (Opana, Numorphan) Sufentanil (Sufenta) Tapentadol (Nucynta)	Hydrocodone (Vicodin) Methadone (Dolophine) Oxycodone (Percocet, Oxycontin)	Codeine (Codeine; Fioricet with Codeine) Tramadol (Ultram)

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Dosing Guidance

Codeine
Codeine; Fioricet with Codeine

Non-Response to Codeine (CYP2D6: Poor Metabolizer) — ACTIONABLE

Greatly reduced morphine levels are expected, and the patient may not experience adequate pain relief when taking codeine. Avoid prescribing codeine, and consider alternative opioids other than tramadol, or a non-opioid analgesic such as a NSAID or a COX-2 inhibitor. Unless contraindicated, available alternative opioids not sensitive to CYP2D6 function include: fentanyl, morphine, hydromorphone, oxymorphone, and tapentadol.

Hydrocodone
Vicodin

Possible Altered Response to Hydrocodone (CYP2D6: Poor Metabolizer) — INFORMATIVE

Decreased conversion of hydrocodone to the more active metabolite hydromorphone is expected in CYP2D6 poor metabolizers. However, there is insufficient evidence whether poor metabolizers have decreased analgesia when taking hydrocodone. Adequate pain relief can be achieved by increasing the dose in response to pain symptoms. Other opioids not metabolized by CYP2D6 may also be considered (i.e., morphine, oxymorphone, buprenorphine, fentanyl, methadone, and hydromorphone).

Methadone
Dolophine

Possible Sensitivity to Methadone (CYP2B6: Intermediate Metabolizer) — INFORMATIVE

Based on currently available evidence, S-methadone plasma concentrations may increase, resulting in higher risk of cardiac arrhythmias and QTc prolongation. Consider lower starting doses of methadone, and adjust dosing based on the clinical response.

Oxycodone
Percocet, Oxycontin

Possible Altered Response to Oxycodone (CYP2D6: Poor Metabolizer) — ACTIONABLE

Decreased conversion of oxycodone to the more active metabolite oxymorphone is expected in CYP2D6 poor metabolizers. However, there is insufficient evidence whether poor metabolizers have decreased analgesia when taking oxycodone. Adequate pain relief can be achieved by increasing the dose in response to pain symptoms. Other opioids not metabolized by CYP2D6 may also be considered (i.e., morphine, oxymorphone, buprenorphine, fentanyl, methadone, and hydromorphone).

Tizanidine
Zanaflex

Possible Non-Response to Tizanidine (CYP1A2: Normal Metabolizer - Higher Inducibility) — INFORMATIVE

There is little evidence regarding the impact of CYP1A2 genetic variants on tizanidine response. Smokers may be at risk for non-response and may require higher doses. There is an association between high tizanidine plasma concentrations and the risk of hypotension and excessive sedation. Therefore, careful monitoring is recommended during dosing adjustment. Smoking cessation may increase plasma drug levels, leading to excessive hypotension and sedation. Careful monitoring accompanied by dose reduction may be needed in patients who have quit smoking.

Tramadol
Ultram

Non-Response to Tramadol (CYP2D6: Poor Metabolizer) — ACTIONABLE

The patient will not experience adequate pain relief when taking tramadol. Avoid prescribing tramadol, and consider alternative opioids other than codeine or a non-opioid analgesic such as a NSAID or a COX-2 inhibitor. Unless contraindicated, available alternative opioids not sensitive to CYP2D6 function include: fentanyl, morphine, hydromorphone, oxymorphone, and tapentadol.

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Test Details

Gene	Genotype	Phenotype	Clinical Consequences
CYP1A2	*1F/*1F	**Normal Metabolizer - Higher Inducibility**	Consistent with a typical CYP1A2 activity in absence of inducing substances. Rapid Metabolism occurs in presence of inducers such as barbiturates, cruciferous vegetables, carbamazepine, rifampin and smoking.
CYP2B6	*1/*6	**Intermediate Metabolizer**	Consistent with a moderate deficiency in CYP2B6 activity. Potential risk for side effects or loss of efficacy with drug substrates.
CYP2C19	*2/*17	**Intermediate Metabolizer**	Consistent with a moderate deficiency in CYP2C19 activity. Potential risk for side effects or loss of efficacy with drug substrates.
CYP2C9	*1/*1	**Normal Metabolizer**	Consistent with a typical CYP2C9 activity. This test did not identify risks for side effects or loss of efficacy with drug substrates.
CYP2D6	*4/*4	**Poor Metabolizer**	Consistent with a significant deficiency in CYP2D6 activity. Increased risk for side effects or loss of efficacy with drug substrates.
CYP3A4	*1/*1	**Normal Metabolizer**	Consistent with a typical CYP3A4 activity. Caution is advised when prescribing narrow therapeutic index drugs. Alternative drugs or dose adjustment may be required if CYP3A inhibitors or inducers are co-prescribed.
CYP3A5	*3/*3C	**Poor Metabolizer**	Consistent with a poor CYP3A5 activity. This phenotype is the most common in the general population. Caution is advised when prescribing narrow therapeutic index drugs. Alternative drugs or dose adjustment may be required if CYP3A inhibitors or inducers are co-prescribed.
Factor II **Factor V Leiden**	20210G>A GG 1691G>A GG	**No Increased Risk of Thrombosis**	The patient's risk of thrombosis is not increased (average risk of clotting is about 1 in 1000 for anyone in a year). However, because this test cannot find all of the inherited reasons for abnormal clotting, other factors may affect this risk assessment.
MTHFR	1298A>C AC 677C>T CT	**No Increased Risk of Hyperhomocysteinemia**	The patient's reduced MTHFR activity is not a risk factor for hyperhomocysteinemia. Unless other risk factors are present, the patient is not expected to have an increased risk for venous thromboembolism (VTE).
OPRM1	A118G A/A	**Normal OPRM1 Function**	Consistent with a normal OPRM1 receptor signaling efficiency induced by exogenous opioids. This is associated with a good analgesia following standard opioid doses and a poor response to naltrexone.

Alleles Tested: CYP1A2 *1C, *1D, *1E, *1F, *1J, *1K, *1L, *1V, *1W, *3, *5, *6, *7, *8, *11, *15, *16; **CYP2B6** *7, *4, *5, *6, *9, *18, *22; **CYP2C19** *2, *3, *4, *4B, *5, *6, *7, *8, *9, *10, *13, *17; **CYP2C9** *2, *3, *4, *5, *6, *8, *11; **CYP2D6** *2, *3, *4, *4M, *6, *7, *8, *9, *10, *11, *12, *15, *17, *29, *35, *41, *5 (gene deletion), XN (gene duplication); **CYP3A4** *1B, *3, *6, *8, *11, *12, *13, *15, *16A, *16B, *17, *18A, *18B, *22; **CYP3A5** *1D, *2, *3, *3B, *3C, *6, *7, *8, *9; **Factor II** 20210G>A; **Factor V Leiden** 1691G>A; **MTHFR** 677C>T, 1298A>C; **OPRM1** A118G

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Limitation: This test will not detect all the known alleles that result in altered or inactive tested genes. This test does not account for all individual variations in the individual tested. Absence of a detectable gene mutation does not rule out the possibility that a patient has different phenotypes due to the presence of an undetected polymorphism or due to other factors such as drug-drug interactions, comorbidities and lifestyle habits. Technical limitations include the possibility of laboratory error and inaccuracy of the test due to unknown rare variants.

Methodology: Bead array and e-sensor based assays detect listed alleles and most rare variants with known clinical significance and analytical sensitivity and specificity >99%.

Lab Disclaimer: Genesys Diagnostics Inc. has validated the Genotype Test. The performance characteristics of this test were determined by Genesys Diagnostics Inc. This test has been cleared and approved for use by the U.S. Food and Drug Administration.

Translational Software Disclaimer: The information presented on this report is provided as general educational health information. The content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Only a physician, pharmacist or other healthcare professional should advise a patient on the use of the medications prescribed.

The pharmacogenetic assay involves use of reporting software and genotype-phenotype associations performed by Translational Software (www.translationalsoftware.com). The software has not been evaluated by the Food and Drug Administration. The software, and the report generated by the software, is not intended to diagnose, treat, cure, or prevent any disease. A qualified designee within the lab uses Translational Software to generate and subsequently review the report. The pharmacogenetic report is one of multiple pieces of information that clinicians should consider in guiding their therapeutic choice for each patient. It remains the responsibility of the health-care provider to determine the best course of treatment for a patient. Adherence to dose guidelines does not necessarily assure a successful medical outcome.

Report was signed out electronically by [redacted]

GENESYS Diagnostics INC.

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NAME:	[redacted]	SPECIMEN TYPE:	[redacted]	[redacted]
ACC #:	[redacted]	COLLECTION DATE:	[redacted]	
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Comprehensive Pharmacogenetic Report with DDI

Current Patient Medications

Lidocaine, Prazosin, Fentanyl, Percocet, Atorvastatin, Clonazepam, Seroquel

Percocet
Oxycodone

Possible Altered Response to Oxycodone (CYP2D6: Poor Metabolizer) — ACTIONABLE

Decreased conversion of oxycodone to the more active metabolite oxymorphone is expected in CYP2D6 poor metabolizers. However, there is insufficient evidence whether poor metabolizers have decreased analgesia when taking oxycodone. Adequate pain relief can be achieved by increasing the dose in response to pain symptoms. Other opioids not metabolized by CYP2D6 may also be considered (i.e., morphine, oxymorphone, buprenorphine, fentanyl, methadone, and hydromorphone).

Atorvastatin
Lipitor

Normal Myopathy Risk (SLCO1B1: Normal Function) — INFORMATIVE

Atorvastatin plasma concentrations are not expected to increase, and unless other genetic or circumstantial risk factors are present, atorvastatin can be prescribed at standard FDA-recommended starting doses and adjusted based on disease-specific guidelines. (Other myopathy predisposing factors include advanced age (≥65), uncontrolled hypothyroidism, renal impairment, high statin dose, comedications, and female gender.)

Atorvastatin
Lipitor

Normal Response to Atorvastatin (CYP3A4: Normal Metabolizer) — INFORMATIVE

The genotype result indicates that the patient does not carry the CYP3A4*22 allele (this allele is associated with a decreased CYP3A4 enzyme activity). The patient is expected to achieve an optimal lipid control goal with standard atorvastatin dose requirements.

Clonazepam
Klonopin

Normal Response to Clonazepam — INFORMATIVE

Pharmacogenetic guidance: No genetically guided drug selection or dosing recommendations are available.
Polypharmacy guidance: clonazepam is extensively metabolized by CYP3A4 to an amino metabolite that is further acetylated by N-acetyltransferases. This drug should be used with caution when prescribed with CYP3A4 inhibitors or inducers.

Fentanyl
Actiq

Good Response to Fentanyl (OPRM1: Normal OPRM1 Function) — INFORMATIVE

The patient does not carry the OPRM1 118A>G mutation. Acute postoperative and cancer pain: the patient is expected to experience good analgesia at standard fentanyl doses. Because fentanyl has a narrow therapeutic window, it is advised to carefully titrate this drug to a tolerable dose that provides adequate analgesia with minimal side effects.

Seroquel
Quetiapine

Normal Response to Quetiapine — INFORMATIVE

Pharmacogenetic guidance: Quetiapine is predominantly metabolized to several metabolites by CYP3A4. CYP3A5 and CYP2D6 are also responsible for quetiapine metabolism but their role in the overall metabolism of this drug is minor compared to CYP3A4. N-desalkylquetiapine, a pharmacologically active metabolite (responsible of the antidepressant effect) is further metabolized by CYP2D6 and CYP3A4. Preliminary studies have shown that genetic polymorphisms of CYP3A4, CYP2D6 and CYP3A5 enzymes may be responsible in variable exposures to quetiapine and to its active metabolite N-desalkylquetiapine. However, the clinical significance of these changes is not established yet and no genetically guided drug selection or dosing recommendations are available. Quetiapine dose should be titrated based on the clinical response and tolerability of the individual patient. **Polypharmacy guidance**: Quetiapine dose should be reduced to **one sixth of original dose** when co-medicated with a potent CYP3A4 inhibitor (e.g., ketoconazole, itraconazole, indinavir, ritonavir, nefazodone). When the CYP3A4 inhibitor is discontinued, the dose should be increased by 6 fold. Quetiapine dose should be increased up to 5 fold of the original dose when used in combination with a chronic treatment (e.g. > 7-14 days) of a potent CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, St. John's wort etc.). When the CYP3A4 inducer is discontinued, the dose should be reduced to the original level within 7-14 days.

Fentanyl & Clonazepam	Limit prescribing opioid analgesics with CNS depressants such as benzodiazepines to patients for whom alternatives are inadequate.If concurrent use is necessary, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. If starting a CNS depressant (for an indication other than epilepsy) with an opioid analgesic, prescribe a lower initial dose of the CNS depressant than indicated in the absence of an opioid and titrate based upon clinical response. If an opioid analgesic is indicated in a patient already taking a CNS depressant, prescribe a lower dose of the opioid and titrate based upon clinical response.Monitor patients receiving concurrent therapy for unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.	MODERATE
Fentanyl & Seroquel	Limit prescribing opioid analgesics with CNS depressants such as antipsychotics to patients for whom alternatives are inadequate.If concurrent use is necessary, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. If starting a CNS depressant (for an indication other than epilepsy) with an opioid analgesic, prescribe a lower initial dose of the CNS depressant than indicated in the absence of an opioid and titrate based upon clinical response. If an opioid analgesic is indicated in a patient already taking a CNS depressant, prescribe a lower dose of the opioid and titrate based upon clinical response.Monitor patients receiving concurrent therapy for unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.	MODERATE
Percocet & Seroquel	Limit prescribing opioid analgesics with CNS depressants such as antipsychotics to patients for whom alternatives are inadequate.If concurrent use is necessary, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. If starting a CNS depressant (for an indication other than epilepsy) with an opioid analgesic, prescribe a lower initial dose of the CNS depressant than indicated in the absence of an opioid and titrate based upon clinical response. If an opioid analgesic is indicated in a patient already taking a CNS depressant, prescribe a lower dose of the opioid and titrate based upon clinical response.Monitor patients receiving concurrent therapy for unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.	MODERATE
Percocet & Clonazepam	Limit prescribing opioid analgesics with CNS depressants such as benzodiazepines to patients for whom alternatives are inadequate.If concurrent use is necessary, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. If starting a CNS depressant (for an indication other than epilepsy) with an opioid analgesic, prescribe a lower initial dose of the CNS depressant than indicated in the absence of an opioid and titrate based upon clinical response. If an opioid analgesic is indicated in a patient already taking a CNS depressant, prescribe a lower dose of the opioid and titrate based upon clinical response.Monitor patients receiving concurrent therapy for unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.	MODERATE

Unrecognized Medications: *None*

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CLASS	DRUG*	PHARMACOGENETIC RESULTS ✓	⚠	✗	INTERACTING DRUGS
Opioids	*Alfentanil (Alfenta)*	●			⚠ Clonazepam ⚠ Seroquel
	Buprenorphine (Butrans, Buprenex)	●			⚠ Clonazepam ✗ Fentanyl ⚠ Percocet ⚠ Seroquel
	Codeine (Codeine; Fioricet with Codeine)			●	⚠ Clonazepam ⚠ Seroquel
	Dihydrocodeine (Synalgos-DC)	●			⚠ Clonazepam ⚠ Seroquel
	Fentanyl (Actiq)	●			⚠ Seroquel ⚠ Clonazepam
	Hydrocodone (Vicodin)		●		✗ Clonazepam ✗ Seroquel
	Hydromorphone (Dilaudid, Exalgo)	●			⚠ Clonazepam ⚠ Seroquel
	Levorphanol (Levo Dromoran)	●			⚠ Clonazepam ⚠ Seroquel
	Meperidine (Demerol)	●			⚠ Clonazepam ⚠ Seroquel
	Methadone (Dolophine)		●		⚠ Clonazepam ⚠ Seroquel
	Morphine (MS Contin)		●		⚠ Clonazepam ⚠ Seroquel
	Oxycodone (Percocet, Oxycontin)		●		⚠ Clonazepam ⚠ Seroquel
	Oxymorphone (Opana, Numorphan)	●			⚠ Clonazepam ⚠ Seroquel
	Sufentanil (Sufenta)	●			⚠ Clonazepam ⚠ Seroquel
	Tapentadol (Nucynta)	●			⚠ Clonazepam ⚠ Seroquel